

ViroPharma Incorporated
Form 10-K



**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the fiscal year ended December 31, 2011

OR

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from _____ to _____

Commission File Number: 000-21699

VIROPHARMA INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

23-2789550
(I.R.S. Employer
Identification No.)

730 Stockton Drive,
Exton, Pennsylvania
(Address of principal executive offices)

19341
(Zip Code)

Registrant's telephone number, including area code: 610-458-7300

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:

Name of each exchange on which registered:

Common Stock, par value \$0.002

The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:

Title of each class: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined by Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer ☒

Accelerated Filer ☐

Non-accelerated filer ☐

Smaller Reporting Company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The approximate aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$1.2 billion as of June 30, 2011, based upon the closing sale price per share of the Common Stock as quoted on the Global Market segment of the NASDAQ Stock Market on that date.

The number of shares of the registrant's Common Stock outstanding as of February 15, 2012 was 70,726,378 shares.

DOCUMENTS INCORPORATED BY REFERENCE

As stated in Part III of this Annual Report on Form 10-K, portions of the registrant's definitive proxy statement for the registrant's 2012 Annual Meeting of Stockholders scheduled to be held on May 21, 2012 are incorporated by reference in Part III of this Annual Report on Form 10-K.

VIROPHARMA INCORPORATED
FORM 10-K ANNUAL REPORT
For Fiscal Year Ended December 31, 2011
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"ViroPharma," "ViroPharma" plus the design, "Cinryze", CinryzeSolutions and "Vancocin" are trademarks and service marks of ViroPharma or its licensors. We have obtained trademark registration in the United States for the marks in connection with certain products and services. All other brand names or trademarks appearing in this Annual Report on Form 10-K are the property of others.

Unless the context requires otherwise, references in this report to "we," "our," "us," "Company" and "ViroPharma" refer to ViroPharma Incorporated and its subsidiaries.

PART I

ITEM 1. BUSINESS

Overview

ViroPharma Incorporated is a global biotechnology company dedicated to the development and commercialization of products that address serious diseases, with a focus on products used by physician specialists or in hospital settings. We intend to grow through sales of our marketed products, through continued development of our product pipeline, expansion of sales into additional territories outside the United States and Europe, through potential acquisition or licensing of products and product candidates and the acquisition of companies. We expect future growth to be driven by sales of Vancocin, sales of Cinryze®, both domestically and internationally, sales of Buccolam and Plenadren in Europe, and by our primary development programs, including C1 esterase inhibitor and a non-toxicogenic strain of *C. difficile* (VP20621).

We market and sell Cinryze in the United States for routine prophylaxis against angioedema attacks in adolescent and adult patients with hereditary angioedema (HAE). Cinryze is a C1 esterase inhibitor therapy for routine prophylaxis against HAE, also known as C1 inhibitor (C1-INH) deficiency, a rare, severely debilitating, life-threatening genetic disorder. Cinryze was acquired in October 2008 and in January 2010, we acquired expanded rights to commercialize Cinryze and future C1-INH derived products in certain European countries and other territories throughout the world as well as rights to develop future C1-INH derived products for additional indications. In June 2011, the European Commission (EC) granted us Centralized Marketing Authorization for Cinryze in adults and adolescents with HAE for routine prevention, pre-procedure prevention and acute treatment of angioedema attacks. The approval also includes a self administration option for appropriately trained patients. We have begun to commercialize Cinryze in Europe and continue to evaluate our commercialization plans in countries where we have distribution rights.

We also market and sell Vancocin HCl capsules, the oral capsule formulation of vancomycin hydrochloride, in the U.S. and its territories. Vancocin is indicated for the treatment of *C. difficile*-associated diarrhea (CDAD). Vancocin capsules are also used for the treatment of enterocolitis caused by *Staphylococcus aureus*, including methicillin-resistant strains. On December 14, 2011, we announced the modernization of labeling for Vancocin capsules made effective through the FDA's approval of a supplemental new drug application (sNDA).

In May 2010, we acquired Auralis Limited, a UK based specialty pharmaceutical company. In connection with the Auralis acquisition, we acquired Buccolam® (Oromucosal Solution, Midazolam [as hydrochloride]). In September 2011, the EC granted a Centralized Pediatric Use Marketing Authorization (PUMA) for Buccolam, for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from 3 months to less than 18 years of age. We have begun to commercialize Buccolam in Europe.

On November 15, 2011, we acquired a 100% ownership interest in DuoCort Pharma AB (DuoCort), a private company based in Helsingborg, Sweden focused on improving glucocorticoid replacement therapy for treatment of adrenal insufficiency, or Addison's disease (AD). The acquisition of DuoCort further expands our orphan disease commercial product portfolio. On November 3, 2011, the EC granted European Marketing Authorization for Plenadren® (hydrocortisone, modified release tablet), an orphan drug for treatment of adrenal insufficiency in adults, which will bring these patients their first pharmaceutical innovation in over 50 years. We anticipate commercial launch of Plenadren in the EU in late 2012 or early 2013. A named patient program is currently available to patients in Europe, which we expect to continue until commercial launch of Plenadren, which is anticipated in late 2012 or early 2013.

Our product development portfolio is primarily focused on three programs, C1 esterase inhibitor [human], VP20621 and VP-20629.

We are working on developing further therapeutic uses, potential additional indications in other C1 mediated diseases, and alternative modes of administration for C1 esterase inhibitor. We intend to conduct ViroPharma

sponsored studies and investigator-initiated studies (IIS) to identify further therapeutic uses and potentially expand the labeled indication for Cinryze to include other C1 mediated diseases, such as Antibody-Mediated Rejection (AMR) and Delayed Graft Function (DGF). Additionally, in May 2011, Halozyme Therapeutics (Halozyme) granted us an exclusive worldwide license to use Halozyme's proprietary Enhance™ technology, a proprietary drug delivery platform using Halozyme's recombinant human hyaluronidase enzyme (rHuPH20) technology in combination with a C1 esterase inhibitor. We intend to apply rHuPH20 initially to develop a subcutaneous formulation of Cinryze for routine prophylaxis against attacks of HAE. In September 2011, we initiated a Phase 2 study to evaluate the safety, and pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20.

We are also developing VP20621 for the treatment and prevention of CDAD. In May 2011, we initiated a Phase 2 dose-ranging clinical study to evaluate the safety, tolerability, and efficacy of VP 20621 for prevention of recurrence of CDAD in adults previously treated for CDAD.

On September 30, 2011, we entered into a license agreement for the worldwide rights of Intellect Neurosciences, Inc. (INS) to its clinical stage drug candidate, VP-20629, which we expect to develop for the treatment of Friedreich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease. VP-20629, or indole-3-propionic acid, is a naturally occurring, small molecule that has potent anti-oxidant properties that can protect against neurodegenerative disease. In a recent Phase 1 safety and tolerability study conducted in the Netherlands, VP-20629 was demonstrated to be safe and well tolerated at all dose levels tested. We expect to initiate a phase 2 study within 12 to 18 months of the date of the agreement, after completion of longer-term toxicology studies. We intend to file for Orphan Drug Designation upon review of the phase 2 proof of concept data.

In addition to these programs, we have several other assets that we may make additional investments in. These investments will be limited and dependent on our assessment of the potential future commercial success of or benefits from the asset. These assets include maribavir for CMV, recombinant C1-INH and other compounds.

On December 22, 2011, we entered into an exclusive Development and Option Agreement with Meritage Pharma, Inc. (Meritage), a private company based in San Diego, CA focused on developing oral budesonide suspension (OBS) as a treatment for eosinophilic esophagitis (EoE). OBS was granted Orphan Drug Designation by the FDA in June of 2011 for the treatment of patients with eosinophilic esophagitis and Meritage conducted a Phase 2 placebo controlled dose-ranging clinical trial in pediatric patients with EoE. Meritage will continue to be responsible for additional clinical development of OBS until the option is exercised or expires.

We intend to continue to evaluate in-licensing or other opportunities to acquire products in development, or those that are currently on the market. We plan to seek products that treat serious or life threatening illnesses with a high unmet medical need, require limited commercial infrastructure to market, and which we believe will provide both revenue and earnings growth over time.

We were incorporated in Delaware in September 1994 and commenced operations in December 1994. Our executive offices are located at 730 Stockton Drive, Exton, Pennsylvania 19341, our telephone number is 610-458-7300 and our website address is www.viropharma.com. Information contained on our website is not incorporated into this Annual Report on Form 10-K or any other filings we make with the SEC.

The following chart generally describes our approved products:

<u>Product</u>	<u>Marketplace</u>	<u>Disease</u>	<u>Program Indication</u>	<u>Product Status</u>
Cinryze – IV . .	US	HAE	Prophylaxis	Marketed
Vancocin . . .	US	CDAD	Treatment	Marketed
Cinryze – IV . .	EU	HAE	Prophylaxis,	Marketed
			pre-procedural and acute	
Buccolam . . .	EU	Pediatric Epilepsy	Treatment	Marketed
Plenadren . . .	EU	AD	Treatment	MAA Approved

The following chart generally describes our investigational products:

<u>Product</u>	<u>Marketplace</u>	<u>Disease</u>	<u>Proposed Indication</u>	<u>Product Status</u>
C1 esterase inhibitor [human] – IV	ROW*	HAE	Prophylaxis, pre-procedural and acute	Filing/Pre-filing
Non-toxicogenic strain of C. difficile (VP20621)	Worldwide	CDAD	Treatment and prevention	Phase 2
C1 esterase inhibitor [human] – subcutaneous administration	Worldwide	HAE	Prophylaxis	Phase 2
C1 esterase inhibitor [human] – antibody- mediated rejection	Worldwide	AMR	Treatment	Phase 2
C1 esterase inhibitor [human] – delayed graft function	Worldwide	DGF	Treatment	Entering Phase 2
C1 esterase inhibitor [human] – IV	Worldwide	Additional indications under evaluation		Preclinical
VP-20629	Worldwide	FA	Treatment	Phase 1

* ROW is defined in the Strategic Relationships section of the document.

Marketed Products

Cinryze

The FDA granted approval for Cinryze in October 2008 for routine prophylaxis against attacks in adolescent and adult patients with hereditary angioedema (HAE). In June 2011, the EC granted us Centralized Marketing Authorization for Cinryze in adults and adolescents with HAE for routine prevention, pre-procedure prevention and acute treatment of angioedema attacks. HAE is a genetic disorder characterized by episodes of edema (swelling) in the extremities, face, abdomen, and airway passages. The majority of patients have episodes of severe abdominal pain, nausea and vomiting that is caused by swelling in the intestinal wall. Attacks that involve the face and throat must be taken seriously and medical treatment should be sought without delay. Swelling of the throat can close the air passage and cause death by suffocation. The mortality rate from untreated airway obstruction has been reported to be over 40% with death most frequently caused by asphyxiation due to airway closure. The course of the disease is diverse and unpredictable, even within a single patient over his or her lifetime. Swelling caused by HAE usually lasts for 24-72 hours, but the length of an attack can range from four hours to four days. On average, patients experience approximately one attack per month, but the frequency is highly variable.

HAE is caused by a defective gene for C1 inhibitor (C1-INH), and this defect is passed on in families, such that a child has a 50% chance of inheriting this disease if one parent is affected. The absence of family history, however, does not rule out HAE diagnosis, and as many as 20% of HAE cases involve patients who appear to have had a spontaneous mutation of the C1-INH gene. This genetic defect results in the production of either inadequate levels or poorly functioning C1-INH protein.

C1-INH is a normal constituent of human blood and primarily regulates activation of key inflammatory and coagulation biochemical pathways, specifically the contact and complement pathways in addition to the fibrinolytic system. Regulation of these systems is performed through the formation of complexes between pathway proteinase enzyme and C1-INH, resulting in inactivation of both and consumption of C1-INH. HAE patients have low levels of endogenous or functional C1-INH. Although the events that induce angioedema attacks in HAE patients are not well defined, it is thought that increased blood vessel permeability leading to swelling and the clinical manifestations of HAE attacks are mediated primarily through contact system activation. Administration of Cinryze increases plasma levels of C1-INH activity. Increased levels of functional

C1-INH are thought to suppress contact system activation through the inactivation of plasma kallikrein and factor XIIa, preventing the generation of bradykinin, a natural peptide thought to be responsible for modulation of blood vessel permeability.

Because HAE is rare and has a wide variability in disease expression, it is not uncommon for patients to remain undiagnosed or misdiagnosed for many years. Many patients report that their frequent and severe abdominal pain was inappropriately diagnosed as psychosomatic. Although rare, HAE is a disease with potentially catastrophic consequences for those affected. Aside from the potentially fatal acute respiratory compromise, unnecessary exploratory surgery has been performed on patients experiencing gastrointestinal edema because abdominal HAE attacks mimic conditions requiring surgery.

Traditionally, HAE has been classified into two types (I and II). The most common form of the disease, Type I, is characterized by low levels of C1-INH and affects about 85% of patients, whereas Type II HAE affects 15% of patients and is characterized by poorly functioning C1-INH. A third type of HAE has been identified in which the abnormal C1-INH protein binds to albumin, effectively reducing the amount of functional C1-INH.

Current Treatments of HAE

Treatment of HAE can be categorized as: (i) mitigation or acute treatments to remedy the symptoms of infrequent episodic acute attacks; and (ii) preventive or prophylactic treatments for patients severely affected by HAE. Current therapies primarily focus upon treating the symptoms of an acute attack. Two therapeutic agents that can be used for treatment of acute attacks were approved by the FDA in 2009, a kallikrein inhibitor and a C1-INH. In January 2012, the FDA approved a label expansion for the self-administration of a competitor's C1-INH for facial and abdominal attacks and also indicates it to treat life-threatening laryngeal HAE attacks. Additionally, in August 2011, the FDA approved a self-administered icatibant for treatment of acute attacks of HAE in adults 18 years of age and older. For swelling of the intestinal wall, which can cause debilitating pain, narcotics such as morphine and antiemetics for nausea are often given. For severe laryngeal swelling, which can be life threatening, rescue therapy such as intubation or tracheotomy may be required. The use of fresh frozen plasma, which contains C1-INH but which also contains a wide variety of other factors that may activate multiple inflammatory pathways and exacerbate an attack, is also used in some instances.

Cinryze is the only FDA approved C1-INH product for prevention of HAE attacks. Prior to the approval of Cinryze, patients who experience more than one attack per month have historically been treated with anabolic steroids that reduce the frequency of attacks of edema. The most commonly used steroids are alpha-alkylated androgens. Use of such anabolic steroids can have numerous side effects ranging from hepatotoxicity (liver toxicity), virilization (development of male sexual characteristics in a female), weight gain, acne and hirsutism (unwanted hair growth).

The FDA granted Cinryze seven years of marketing exclusivity for routine prophylaxis of HAE upon FDA approval in October 2008 pursuant to the Orphan Drug Act. The Office of Orphan Products Development originally granted orphan drug designation for Cinryze on July 16, 2004. We are currently conducting a phase 4 study to evaluate the safety and effect of escalating doses of Cinryze as prophylactic therapy, which was a post approval requirement of the FDA.

C1-INH concentrate has been marketed to HAE patients for acute treatment in Europe for 25 years. Our ability to compete in this marketplace is contingent upon our success in differentiating Cinryze IV over existing C1-INH products.

Vancocin

In November 2004, we acquired all rights in the U.S. and its territories to manufacture, market and sell Vancocin, as well as rights to certain related vancomycin products, from Eli Lilly and Company (Lilly). Lilly retained its

rights to Vancocin outside of the U.S. and its territories. Vancocin is indicated for the treatment of *C. difficile*-associated diarrhea (CDAD). Vancocin also is used for the treatment of enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains). Both are potentially serious infections of the gastrointestinal (GI) tract. *S. aureus* enterocolitis is rare; accordingly, CDAD is the indication that accounts for the significant majority of Vancocin's use.

CDAD is an infection of the GI tract. The clinical manifestations, ranging from diarrhea to toxic megacolon and sometimes death, are a result of toxins produced by the bacterium that cause inflammation in the colon. Hospitalized patients, those residing in long-term care centers, those greater than 65 years of age, and patients that have received broad-spectrum antibiotic therapy, are at greatest risk to acquire CDAD.

CDAD is not a nationally reportable disease and as such it is difficult to estimate the actual incidence of disease with precision. Based on reports from the Centers for Disease Control and Prevention (CDC) and peer-reviewed publications, we estimate that at least 500,000 patients were affected by CDAD in 2008. From 2004 to 2008, many clinicians reported treating increasing numbers of patients with severe CDAD and increased mortality rates. Clinicians have also noted that some patients progressed from mild/moderate disease to severe disease or death more rapidly than had previously been observed. The overall incidence of CDAD may have plateaued or even decreased since 2008, however reliable data on current incidence are limited.

Although the causes for this change in CDAD remain under active investigation, the CDC has postulated that a combination of changes in antibiotic use and infection control practices, along with the emergence of a hypervirulent strain of *C. difficile*, are likely contributors to the increased incidence seen during the 2004 to 2008 time period. As of late 2008, this strain (referred to as the toxinotype III, BI, or NAP1/027 strain) has been identified in at least 40 states in the U.S.

Historically, metronidazole has been commonly used as first-line treatment for CDAD, while Vancocin has been reserved for those patients who have failed metronidazole, have recurrent disease, or who are suffering from severe CDAD. In the 2010 Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA), oral vancomycin was recommended for the treatment of severe CDI and severe complicated CDI. We believe that changes in the epidemiology of CDAD, in particular the increasing frequency of severe disease, and data suggesting that failure or relapse occur more commonly in patients treated with metronidazole and the updated Clinical Practice Guidelines have led to an increase in the use of Vancocin. In May 2011, FDA approved Optimer Pharmaceuticals' product, Dificid® (fidaxomicin), for the treatment of CDAD. It is too early in the launch cycle to project the impact that fidaxomicin will have on CDI treatment protocols.

In December 2008, FDA changed OGD's 2006 bioequivalence recommendation, which we have opposed since its original proposal in March 2006, by issuing draft guidance for establishing bioequivalence to Vancocin which would require generic products that have the same inactive ingredients in the same quantities as Vancocin ("Q1 and Q2 the same"), and that meet certain other conditions, to demonstrate bioequivalence through comparative in vitro dissolution testing. Under this latest proposed method, any generic product that is not Q1 and Q2 the same as Vancocin would need to conduct an in vivo study with clinical endpoints to demonstrate bioequivalence with Vancocin. On August 4, 2009 the FDA's Pharmaceutical Science and Clinical Pharmacology Advisory Committee voted in favor of the portion of the OGD's 2008 draft guidelines on bioequivalence for Vancocin that restricts in vitro bioequivalence testing for generic products that are, among other things, Q1 and Q2 the same as Vancocin.

On December 14, 2011, we announced the modernization of labeling for Vancocin Capsules made effective through the FDA's approval of a supplemental new drug application (sNDA).

Through the sNDA approval, Vancocin's label for the first time includes clinical safety and efficacy data for the use of Vancocin capsules in treating *Clostridium difficile*. Vancocin's labeling now reflects safety and efficacy

data from 260 patients with CDAD treated with Vancocin in two pivotal studies of Genzyme Corporation's investigational drug, tolevamer. We purchased exclusive rights to the two studies from Genzyme for which we will pay Genzyme royalties of 10 percent, 10 percent and 16 percent on net sales of Vancocin for the three year period following the approval of the sNDA.

As a result of the sNDA approval, we believe Vancocin meets the requirements for three years of exclusivity, and that generic vancomycin capsules will not be approved during this period. Under FDA's regulations, labeling changes based on new clinical investigations that are essential to approval of the sNDA and to which the applicant has exclusive rights may be entitled to three years of exclusivity, and generic drug labeling cannot include information protected by such three-year exclusivity. A generic may seek approval by omitting labeling protected by three-year exclusivity; however, if such omissions render the generic drug less safe or effective, it cannot be approved until the three-year exclusivity expires.

We believe that attempting to omit Vancocin labeling changes protected by exclusivity would render generic versions of Vancocin less safe and effective. However, ultimately, the decision on a grant of three-year exclusivity and its effect on generic vancomycin capsule approvals resides with the FDA.

If FDA's proposed bioequivalence method for Vancocin becomes effective, and either FDA does not agree that our labeling changes made effective through our sNDA warrant exclusivity, or FDA acknowledges such exclusivity but nonetheless determines that generic products would be no less safe or effective in the absence of such labeling changes, then the time period in which a generic competitor could be approved would be reduced and multiple generics may enter the market. The approval of generic copies of Vancocin would materially impact our operating results, cash flows and possibly intangible asset valuations. This could also result in a reduction to the useful life of the Vancocin-related intangible assets. Management currently believes there are no indicators that would require a change in useful life as management believes that Vancocin will continue to be utilized along with generics that may enter the market, and the number of generics and the timing of their market entry is unknown.

Buccolam

In May 2010, we acquired Auralis Limited, a UK based specialty pharmaceutical company. In connection with the Auralis acquisition, we acquired Buccolam® (Oromucosal Solution, Midazolam [as hydrochloride]). In September of 2011, the European Commission granted a Centralized Pediatric Use Marketing Authorization (PUMA) for Buccolam, for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from 3 months to less than 18 years of age. We have begun to commercialize Buccolam in Europe.

Seizures occur because of sudden and abnormal electrical activity in the brain. There are many causes of seizures affecting pediatric patients; many are the result of epilepsy, but other triggers can include medicines, head injuries, certain diseases, and high fevers (called 'febrile seizures'). Febrile seizures are the most common type of seizure in children; approximately one in every 25 children will have at least one febrile seizure, and more than one-third of these children will have additional febrile seizures before they outgrow the tendency to have them. Epilepsy is among the most common childhood neurological disorders in developed countries, affecting nearly one percent of the population. There are approximately six million people affected by epilepsy in Europe; nearly one million European children and adolescents have active epilepsy. Epilepsy commonly causes physical manifestations including neurological and muscle destruction and degradation of renal function, as well as numerous negative cognitive, behavioral and neurological effects. Seizures can last from a few seconds to several minutes or longer in some cases. If left untreated, seizures can lead to status epilepticus (SE) and patients may require hospitalization and intensive care.

Buccolam is oromucosal midazolam provided in an individual dose formulation for buccal delivery. It is provided as a convenient, portable, ready to use, pre-filled oral syringe containing an age-specific dose. Buccolam is approved throughout the European Union and the EEA for treatment of prolonged, acute, convulsive

seizures in infants, toddlers, children and adolescents, from three months to less than 18 years of age. Buccolam must only be used by parents/carers where the patient has been diagnosed to have epilepsy.

Plenadren

On November 15, 2011, we acquired a 100% ownership interest in DuoCort Pharma AB (DuoCort), a private company based in Helsingborg, Sweden focused on improving glucocorticoid replacement therapy for treatment of adrenal insufficiency, or Addison's disease (AD). The acquisition of DuoCort further expands our orphan disease commercial product portfolio. On November 3, 2011, the European Commission (EC) granted European Marketing Authorization for Plenadren® (hydrocortisone, modified release tablet), an orphan drug for treatment of adrenal insufficiency in adults, which will bring these patients their first pharmaceutical innovation in over 50 years. We anticipate commercial launch of Plenadren in the EU in late 2012 or early 2013. A named patient program is currently available to patients in Europe, which we expect to continue until commercial launch.

Plenadren is a dual release hydrocortisone replacement therapy designed to better mimic the normal physiological cortisol profile in order to improve outcomes for patients suffering from adrenal insufficiency. Plenadren is given as an oral tablet once daily. It has an outer layer releasing hydrocortisone immediately and an inner core releasing the rest of the drug more slowly during the day.

Adrenal insufficiency (AI) is a disorder caused by dysfunction of the adrenal gland resulting in low levels of the hormone cortisol, which normally follows a circadian rhythm and regulates many critical body functions. To survive, AI patients need replacement therapy with glucocorticoids (usually hydrocortisone). Because it is a chronic condition, they require this life-saving therapy throughout their lives. Primary AI is referred to as Addison's disease, which affects up to 15 in every 100,000 people. Common symptoms of Addison's disease include fatigue, muscle weakness, fever, weight loss, difficulty in standing up, changes in personality, and gastrointestinal involvement. Severe adrenal insufficiency, which can manifest as shock (very low blood pressure with loss of consciousness), dehydration, and imbalance of sodium and potassium levels, can be life threatening. These cases of adrenal crisis (sometimes called 'Addisonian crisis') can occur after a significant stress such as infection or trauma, and can be fatal if not promptly diagnosed and treated with glucocorticoid therapy. To maintain a reasonable quality of life, these patients rely on cortisol replacement therapy. Because it is a chronic condition, these patients require this therapy throughout their entire lives.

Product Pipeline

Our product development portfolio is primarily focused on three programs: Cinryze (C1 esterase inhibitor [human]) for management of hereditary angioedema, VP 20621 for the management of *C. difficile* infection (CDAD) and VP20629, which we expect to develop for the treatment of Friedreich's Ataxia. We are also working on developing alternative modes of administration for Cinryze and additional therapeutic uses for C1 esterase inhibitor in other complement-mediated diseases.

HAE Program

Cinryze IV—Outside the United States and Europe

In January 2010, we obtained expanded rights to commercialize Cinryze in certain countries in Europe and ROW as well as rights to develop future C1-INH derived products for additional indications. We continue to evaluate our commercialization plans in countries outside of the United States and Europe where we have distribution rights. We are currently in the process of identifying the steps necessary to launch in other territories where we have distribution rights and have made regulatory filings in several countries.

Cinryze IV—Other formulations and other complement-mediated diseases

We are currently evaluating with our partner Sanquin, the feasibility of other (non-IV) formulations and modes of administration for Cinryze. We have conducted a Phase 1 study utilizing subcutaneous administration of

Cinryze, and results of this study supported the conduct of a Phase 2 study. In October 2010 we announced the completion of enrollment in this Phase 2 study which is designed to evaluate the safety, pharmacokinetics and pharmacodynamics of subcutaneous versus intravenous administration of Cinryze in adolescent and adult subjects with hereditary angioedema (HAE).

In May 2011, Halozyme Therapeutics (Halozyme) granted us an exclusive worldwide license to use Halozyme's proprietary Enhance™ technology, a proprietary drug delivery platform using Halozyme's recombinant human hyaluronidase enzyme (rHuPH20) technology in combination with a C1 esterase inhibitor. We intend to apply rHuPH20 initially to develop an subcutaneous formulation of Cinryze for routine prophylaxis against attacks of HAE. In September 2011, we initiated a Phase 2 study to evaluate the safety, and pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20.

We continue to evaluate Cinryze for additional therapeutic applications and potential indications in other complement-mediated diseases. Our initial focus includes investigating Cinryze in transplant patients, and in the latter part of 2011, we initiated a pilot study to evaluate Cinryze for the treatment of antibody-mediated rejection following certain high-risk kidney transplants.

CDAD Program

VP20621

In February 2006, we announced that we had entered into a licensing agreement with Dr. Dale Gerding, of the Hines VA, for the rights to develop a non-toxigenic strain of *C. difficile* (VP 20621) for the treatment and prevention of CDAD. Under the license agreement, we are required to make royalty payments to Dr. Gerding based on a low single digit percentage of our net sales of the product. If certain milestones are achieved, we will be obligated to pay Dr. Gerding additional milestone payments if and when certain regulatory developments are achieved, in an aggregate amount equal to \$850,000 in total, with no single milestone payment exceeding \$250,000. The license agreement will remain in effect for ten years from the date any product is first commercialized, on a country-by-country basis, unless earlier terminated. The agreement contains a standard early termination provision which provides for early termination by either party in the event certain conditions have occurred, including, but not limited to, either party's breach of the agreement, either party's filing for bankruptcy or either party making an assignment for the benefit of its creditors.

We plan to initially focus our efforts on the opportunity to prevent recurrence of CDAD, using oral administration of VP 20621 spores. According to published literature, approximately 20 to 30 percent of patients suffering from CDAD will have at least one episode of relapse of disease. The goal of this VP20621 program is to prevent such recurrence of disease using a novel non-antibiotic approach. The underlying concept of this approach is to first treat the disease with an effective product like Vancocin and eradicate the dangerous toxin-producing *C. difficile* which causes severe CDAD. The treated patient could potentially then be dosed with oral VP20621 to re-colonize the GI tract and prevent the pathogenic *C. difficile* bacteria from re-infecting the colon until normal GI flora returns and the patient is no longer susceptible to disease.

In September 2010 we announced results of a completed Phase 1 study which was designed to determine the safety and tolerability of VP20621 dosed orally as single and repeat escalating doses in healthy young (18 to 45 years of age) and older (60 years of age and older) adults. After VP20621 was shown to be generally well tolerated following single and repeat doses in younger and older healthy subjects, we also performed repeat dosing in older adults following exposure to oral antibiotic. Subjects above 60 years of age were pre-dosed with oral vancomycin to disrupt their gastrointestinal flora and render them potentially susceptible to *C. difficile* colonization; these subjects were subsequently given either placebo or VP20621 doses of $10^{(4)}$, $10^{(6)}$, or $10^{(8)}$ spores once daily for 14 days. The study demonstrated that VP20621 was generally well tolerated at all dose levels; there were no serious or severe adverse events, and no discontinuations from study drug due to adverse events. All 27 volunteers (100%) who were given VP20621 had positive non-toxigenic *C. difficile* stool cultures

by day 6, suggesting that VP20621 rapidly colonizes the susceptible GI tract. No subject dosed with VP20621 tested positive for toxin-producing strains of *C. difficile* during the 28-day study period. By comparison, 5 of 9 subjects (56%) who received placebo (i.e. did not receive VP20621) tested positive for either toxin-negative or toxin-positive *C. difficile* during the study period. Based on these results, during the second half of 2011, we started a Phase 2 clinical trial for the prevention of recurrence of CDAD in patients recently treated with an antibiotic for CDAD.

FA Program

VP-20629

On September 30, 2011, we entered into a license agreement for the worldwide rights of Intellect Neurosciences, Inc. (INS) to its clinical stage drug candidate, VP-20629, which we expect to develop for the treatment of Friedreich's Ataxia (FA).

Friedreich's Ataxia is a rare hereditary disease caused by a mutation in a gene which encodes frataxin, a protein essential for proper functioning of mitochondria, the energy pumps of the cell. In the absence of frataxin, iron in the cytoplasm builds up and causes free radical damage. The disease causes progressive damage to the nervous system, resulting in symptoms ranging from gait disturbance to speech problems; it can also lead to heart disease and diabetes. Ataxia in general refers to the inability to coordinate voluntary muscular movements. The ataxia of Friedreich's ataxia results from the degeneration of nerve tissue in the spinal cord, in particular sensory neurons essential for directing muscle movement of the arms and legs. The spinal cord becomes thinner and nerve cells lose some of their myelin sheath. The primary sites of pathology are the spinal cord and peripheral nerves. Symptoms typically begin sometime between the ages of 5 and 15 years, but may occur in patients between the ages of 20 to 30. The disease usually presents with progressive staggering or stumbling and frequent falling. The symptoms are slow and progressive with a median age of death at 35 years old. Friedreich's Ataxia is the most common form of hereditary ataxia, and is thought to affect about 1 in every 50,000 people or approximately 6,000 patients in the United States. Currently there are no FDA approved drugs for FA.

VP-20629, or indole-3-propionic acid, is a naturally occurring, small molecule that has potent anti-oxidant properties that can protect against neurodegenerative disease. In a recent Phase 1 safety and tolerability study conducted in the Netherlands, VP-20629 was demonstrated to be safe and well tolerated at all dose levels tested. ViroPharma expects to initiate a phase 2 study within 12 to 18 months from the date of the agreement, after completion of longer term toxicology studies. ViroPharma intends to file for Orphan Drug Designation upon review of the phase 2 proof of concept data.

Other Assets

In addition to the programs described above, we have several other assets in which we may make additional investments. These investments will be dependent on our assessment of the potential future commercial success of or benefits from the asset. These assets include maribavir for CMV, and other compounds. We will continue to incur costs associated with our other development assets for direct research and development costs for medicinal products which will address unmet medical needs such as our current evaluation of a recombinant C1-INH technology which may be included in future clinical studies.

Recent Business Development Activities

We intend to continue to evaluate in-licensing or other opportunities to acquire development stage or marketed products. We plan to seek products that treat serious or life threatening illnesses with a high unmet medical need, require limited commercial infrastructure to market, and that have the potential to provide both top and bottom line growth over time.

Competition for products currently in clinical development, or that are currently on the market, is intense and may require significant resources. There is no assurance that we will be successful in acquiring such products, or that such products can be acquired on terms acceptable to us. Additionally, if we are successful in acquiring a marketed product, we may have to expand our sales and marketing infrastructure both in the US and internationally. There is no assurance that we would be successful in expanding our commercial capabilities, that we would be able to penetrate the markets for any such products or that we could achieve market acceptance of our products. The costs associated with evaluating or acquiring any additional product or product candidate can vary substantially based upon market size of the product, the commercial effort required for the product, the product's current stage of development, and actual and potential generic and non-generic competition for the product, among other factors. Due to the variability of the cost of evaluating or acquiring business development candidates, it is not feasible to predict what our actual evaluation or acquisition costs would be, if any, however, the costs could be substantial. There are also no assurances that we will be able to obtain financing for acquiring such products or to expanding our operations to realize the products potential.

On December 22, 2011, we entered into an exclusive development and option agreement with Meritage Pharma, Inc. (Meritage), a private company based in San Diego, CA focused on developing oral budesonide suspension (OBS) as a treatment for eosinophilic esophagitis (EoE). OBS is a proprietary formulation that is viscous and is designed to coat the esophagus with budesonide where it acts topically. Budesonide is an anti-inflammatory corticosteroid that is the active pharmaceutical ingredient in several products approved by the FDA, including products for the treatment of pediatric asthma, allergic rhinitis and Crohn's disease. The FDA has granted Orphan Drug Status designation to OBS for the treatment of eosinophilic esophagitis. In addition, OBS has pending patent applications, which may result in patent protection to approximately 2028. EoE occurs when eosinophils, a type of white blood cell involved in allergic reactions, infiltrate the surface of the esophagus. Eosinophil infiltration leads to inflammation of the esophagus and is believed to cause tissue remodeling and fibrosis if left untreated. There are no approved products for the treatment of EoE. There are approximately 160,000 patients diagnosed with EoE in the U.S.

We have an exclusive option to acquire Meritage, at our sole discretion, by providing written notice at any time during the period from December 22, 2011 to and including the date that is the earlier of (a) the date that is 30 business days after the later of (i) the receipt of the final study data for the Phase 2 study and (ii) identification of an acceptable clinical end point definition for a pivotal induction study agreed to by the FDA. As consideration for the option, we paid an initial \$7.5 million and have agreed to provide Meritage up to an additional \$12.5 million for the development of OBS. Meritage will utilize the funding to conduct additional Phase 2 clinical assessment of OBS. If we exercise this option, we have agreed to pay \$69.9 million for all of the outstanding capital stock of Meritage. Meritage stockholders could also receive additional payments of up to \$175 million, upon the achievement of certain clinical and regulatory milestones.

On November 15, 2011, we acquired a 100% ownership interest in DuoCort Pharma AB (DuoCort), a private company based in Helsingborg, Sweden focused on improving glucocorticoid replacement therapy for treatment of adrenal insufficiency, or Addison's Disease (AD). We paid approximately 213 million Swedish Krona (SEK) or approximately \$32.1 million in upfront consideration. We have also agreed to make additional payments ranging from SEK 240 million up to SEK 860 million or approximately \$35 million to \$124 million, contingent on the achievement of certain milestones. Up to SEK 160 million or approximately \$24 million of the contingent payments relate to specific regulatory milestones; and up to SEK 700 million or approximately \$105 million of the contingent payments are related to commercial milestones based on the success of the product. As part of the closing of this transaction, we also paid approximately SEK 9.3 million or \$1.4 million to certain of DuoCort's creditors. We incurred approximately \$1.4 million of transaction cost as part of this acquisition.

On September 30, 2011, we entered into an exclusive license agreement with Intellect Neurosciences, Inc. and Intellect USA, Inc. (together, INS) whereby INS grants us an exclusive license and an exclusive sublicense of its rights pursuant to a license agreement with New York University and South Alabama Medical Science Foundation for the worldwide rights to its clinical stage drug candidate, indole-3-propionic acid, also known as

VP-20629, which we expect to develop for the treatment of Friedreich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease. Under the terms of the agreement, we have exclusive worldwide rights to develop and commercialize VP-20629 for the treatment, management or prevention of any disease or condition covered by Intellect's patents. We paid INS a \$6.5 million up-front licensing fee and may pay additional milestones up to \$120 million based upon defined events. We will also pay a tiered royalty of up to a maximum percentage of low teens, based on annual net sales.

In May 2011, Halozyme Therapeutics (Halozyme) granted us an exclusive worldwide license to use Halozyme's proprietary Enhance™ technology, a proprietary drug delivery platform using Halozyme's recombinant human hyaluronidase enzyme (rHuPH20) technology in combination with a C1 esterase inhibitor. Under the terms of the license agreement, we paid Halozyme an initial upfront payment of \$9 million. In the fourth quarter of 2011, we made a milestone payment of \$3 million related to the initiation of a Phase 2 study begun in September 2011 to evaluate the safety, and pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20. Pending successful completion of an additional series of clinical and regulatory milestones, anticipated to begin during 2012, we may make further milestone payments to Halozyme, which could reach up to an additional \$41 million related to HAE and up to \$30 million of additional milestone payments for three additional indications. Additionally, we will pay an annual maintenance fee of \$1 million to Halozyme until specified events have occurred. Upon regulatory approval, Halozyme will receive up to a 10% royalty on net sales of the combination product utilizing Cinryze and rHuPH20, depending on the existence of a valid patent claim in the country of sale.

Strategic Relationships

Cinryze and Sanquin

Pursuant to the terms of an existing Distribution and Manufacturing Services Agreement between our subsidiary ViroPharma Biologics, Inc. ("VP Biologics") with Stichting Sanquin Bloedvoorziening (Sanquin Blood Supply Foundation) ("Sanquin") (the "Original Sanquin Agreement"), we held (i) the exclusive right to distribute, market, offer for sale, sell, import and promote C1-INH derived from human plasma (including Cinryze) manufactured by Sanquin for the treatment of HAE in all countries in North America and South America (other than the Dutch Overseas Territories, Argentina and Brazil) and Israel, and (ii) a right of first refusal to distribute, market, offer for sale, sell, import and promote C1-INH derived from human plasma manufactured by Sanquin for the treatment of HAE in certain other geographic regions and under certain conditions.

On January 8, 2010, we amended and restated the Original Sanquin Agreement (the "Restated US Agreement"). Pursuant to the terms of the Restated US Agreement, we retained the rights to distribute, market, offer for sale, sell, import and promote C1-INH derived from human plasma (including Cinryze) manufactured by Sanquin for the treatment of HAE in all countries in North America and South America (other than the Dutch Overseas Territories, Argentina and Brazil) and Israel.

The initial term of the Restated US Agreement ends on December 31, 2015. The term will automatically renew for up to eighteen years (comprised of six three-year periods), unless the Restated US Agreement is earlier terminated by either party. Sanquin may terminate this Restated US Agreement by providing written notice to us at least three years prior to the end of the initial term or any subsequent renewal period. We may terminate the Restated US Agreement by providing written notice to Sanquin at least two years prior to the end of the initial term or any subsequent renewal period. Each party may terminate the Restated US Agreement upon written notice in the event of: (i) an uncured material breach of the other party or (ii) the other party is declared insolvent or bankrupt, a voluntary petition of bankruptcy is filed by the other party, the other party makes or executes any assignment for the benefit of creditors or a receiver is appointed to control the business of the other party.

Also, on January 8, 2010 we obtained the exclusive rights to research, develop, import, use, sell and offer for sale C1-INH derived products (other than Ceter) worldwide, other than the Excluded Territory (as defined below) for

all potential indications pursuant to a Manufacturing and Distribution Agreement (Europe and ROW) between our European subsidiary, ViroPharma SPRL (“VP SPRL”) and Sanquin (the “ROW Agreement”). The Excluded Territory includes (i) certain countries with existing distributors of Cinryze, Ceter and Ceter NF namely France, Ireland, the United Kingdom, Egypt, Iran, Israel, Indonesia, Turkey, Argentina and Brazil (the “Third Party Distributors”) and (ii) countries in which Sanquin has historically operated namely, Belgium, Finland, Luxemburg and The Netherlands (including the Dutch Overseas Territories) (the “Precedent Countries” and collectively, the “Excluded Territory”). In the event that any agreement with a third party distributor in the Excluded Territory is terminated, we have a right of first refusal to obtain the foregoing exclusive licenses to the C1-INH derived products with respect to such terminated country.

The initial term of the ROW Agreement will end on December 31, 2019, but shall automatically renew for up to eighteen years (comprised of six three-year periods), unless the ROW Agreement is earlier terminated by either party. Sanquin may terminate the ROW Agreement by providing written notice to us at least three years prior to the end of the initial term or any subsequent renewal period. We may terminate the ROW Agreement by providing written notice to Sanquin at least two years prior to the end of the initial term or any subsequent renewal period. Each party may terminate the ROW Agreement upon written notice to the other in the event of: (i) an uncured material breach of the other party or (ii) in the event that other party (1) applies for or consents to an appointment of a receiver for itself or all or substantially all of its assets, (2) makes an assignment for the benefit of creditors, (3) commences a voluntary case or bankruptcy or consents to any bankruptcy or restructuring relief or the appointment of or taking possession of its property in any such proceeding or (4) takes any corporate action to effect any of the foregoing.

In January 2010, both parties established a Joint Steering Committee comprised of an equal number of representatives from each of the parties to the agreements. The Joint Steering Committee shall serve as a forum to establish and discuss progress under, among others, (i) a global commercialization plan; (ii) clinical development programs of ViroPharma and Sanquin early stage research programs; (iii) manufacturing capacity schedules; (iv) pharmacovigilance matters; (v) quality matters; (vi) manufacturing improvement programs; and (vii) regulatory matters.

Subject to certain terms of each of the Restated US Agreement and the ROW Agreement, if we do not use commercially reasonable efforts to file applications for marketing authorization of Cinryze or launch Cinryze in accordance with a commercialization plan for the applicable territories, as approved by the Joint Steering Committee, Sanquin may (upon prior written notice to us) terminate our rights in the applicable country.

In addition, pursuant to the terms of the ROW Agreement, Sanquin may conduct certain early stage research programs (the “Early Stage Research Programs”), and we will provide to Sanquin €1,000,000 (approximately \$1.3 million) per year for a period of five years to support such Early Stage Research Programs. We have a right of first refusal to further develop and commercialize the subject matter of each such Early Stage Research Program worldwide (except for the Excluded Territory) subject to Sanquin’s and its research partners’ right to use any such intellectual property for their internal, non-commercial research purposes. Except for the Early Stage Research Programs, we will be solely responsible for conducting all clinical trials and other development activities necessary to support our efforts to obtain regulatory approval of Cinryze in additional territories as well as any future C1-INH derived products developed pursuant to the ROW Agreement. Sanquin has the right to approve any such clinical trials and development activities through the Joint Steering Committee.

Sanquin may include in its regulatory dossiers improvements to Cinryze for the hereditary angioedema (“HAE”) indication, solely for the marketing and sale of Ceter or Ceter NF in the Excluded Territory. If there are (i) new indications relating to any C1-INH product or (ii) improvements relating to the HAE-indication that cannot be included in Sanquin’s regulatory dossiers, Sanquin will receive a royalty-free license to sell Cinryze or the future product for these new indications or improvements in the Precedent Countries.

Sanquin has agreed to indemnify us and our affiliates for certain losses, except to the extent we have an obligation to indemnify Sanquin. We have agreed to indemnify Sanquin and its affiliates for all losses arising

from (i) our infringement of any third party's intellectual property as a result of the sale of Cinryze or any future C1-INH derived products in the territories covered by the agreements, (ii) a breach by us of the terms of the agreements, (iii) certain tax liabilities and (iv) our negligence or willful misconduct, except, in each case, to the extent Sanquin has an obligation to indemnify us.

Without Sanquin's prior written consent, we shall not enter into a merger, be acquired by or sell substantially all of our assets to a manufacturer and/or distributor of a plasma derived C1 esterase inhibitor or another plasma-derived product approved under applicable law for marketing for the same or comparable clinical indications as Cinryze or any future C1-INH derived products. We may not, without the consent of Sanquin, distribute, market, offer for sale, sell, import or promote any competitive product in the territory covered by the Restated US Agreement until December 31, 2018. In addition, we may not, without the consent of Sanquin, distribute, market, offer for sale, sell, import or promote any competitive product in the territories covered by the ROW Agreement until December 31, 2019.

In the event that VP Biologics has become bankrupt or insolvent and has committed an uncured breach of the Restated US Agreement, Sanquin will immediately obtain VP Biologics' rights to the marketing authorizations for Cinryze obtained by us and the applications for marketing authorization of Cinryze filed by us. ViroPharma Incorporated will guarantee VP Biologics' performance under the Restated US Agreement. In the event that VP SPRL becomes bankrupt or insolvent and commits an uncured breach of the ROW Agreement, Sanquin will immediately obtain our rights to the regulatory approvals for the products obtained by us under the ROW Agreement and the applications for regulatory approval of the product filed by us under the ROW Agreement. ViroPharma Incorporated will guarantee VP SPRL's performance under the ROW Agreement in the event of a bankruptcy.

Vancocin Capsules and Lilly

In November 2004, we acquired all rights in the U.S. and its territories to manufacture, market and sell Vancocin, the oral capsule formulation of vancomycin hydrochloride, as well as rights to certain related vancomycin products, from Lilly. Vancocin is indicated for the treatment of *C. difficile*-associated diarrhea (CDAD). Vancocin capsules are also used for the treatment of enterocolitis caused by *Staphylococcus aureus*, including methicillin-resistant strains. Lilly retained its rights to vancomycin outside of the U.S. and its territories.

We paid Lilly an upfront cash payment of \$116.0 million and were obligated to pay additional purchase price consideration based on annual net sales of Vancocin through 2011. As of December 31, 2011, we have paid an aggregate of \$51.1 million to Lilly in additional purchase price consideration, as our net sales of Vancocin surpassed the maximum obligation level of \$65 million in 2005 through 2011. In June 30, 2011, we satisfied our obligations to Lilly to make additional purchase price consideration payments under the purchase agreement.

In the event we develop any product line extensions, revive discontinued vancomycin product lines (injectable or oral solutions), make improvements of existing products, or expand the label to cover new indications, Lilly would receive a royalty on net sales on these additional products for a predetermined time period.

Vancocin Capsules and Genzyme

On June 12, 2009, we entered into an Exclusive Clinical Study and Data License Agreement with Genzyme Corporation (Genzyme). Under the agreement, we exclusively licensed certain clinical studies that Genzyme has performed and/or sponsored relating to its proprietary product, tolevamer, including the data generated from the clinical studies. In consideration for exclusive rights to the clinical studies and data generated from such clinical studies, we agreed to pay Genzyme royalties of 10%, 10% and 16% on the net sales of Vancocin (vancomycin hydrochloride capsules, USP) for the three year period following approval of a supplemental new drug application to update Vancocin's label based on the data licensed from Genzyme. We will pay lower royalties on

sales of any authorized generic depending on the number of parties selling a generic vancomycin product. The agreement continues in effect unless terminated earlier pursuant to its terms. In addition to standard termination rights, we also may terminate the agreement at any time after the expiration of the royalty term. The royalty term commenced on December 15, 2011, the day following approval by FDA of the sNDA, and will continue until December 15, 2014, the third anniversary.

Cytomegalovirus and GlaxoSmithKline

In August 2003, we entered into a license agreement with GlaxoSmithKline (GSK) under which we acquired worldwide rights (excluding Japan) to an antiviral compound, maribavir, for the treatment of CMV disease. Maribavir is a benzimidazole compound that was in development by GSK for the treatment of CMV retinitis in HIV positive patients.

Under the terms of the agreement, we have exclusive worldwide rights (excluding Japan) to develop and commercialize maribavir for the prevention and treatment of cytomegalovirus infections related to transplant (including solid organ and hematopoietic stem cell / bone marrow transplantation), congenital transmission, and in patients with HIV infection. The patents covering maribavir expire in 2015. We paid GSK a \$3.5 million up-front cash licensing fee and will pay additional milestone payments based upon defined clinical development and regulatory events. In the third quarter of 2006, we recorded a \$3.0 million milestone payment due to GSK associated with the initiation of the phase 3 study of maribavir, which was paid in February 2007. No additional amounts were recorded in 2007. We also will pay royalties to GSK and its licensor on product sales in the U.S. and rest of world (excluding Japan). We will be dependent on GSK to prosecute and maintain the patents related to maribavir, and to file any applications for patent term extension. We also may be dependent on GSK to protect such patent rights. We have the right to sublicense our rights under the agreement, which under certain circumstances requires consent from GSK.

Manufacturing and Distribution

We currently utilize a virtual supply manufacturing and distribution chain in which we do not have our own facilities to manufacture commercial or clinical trial supplies of drugs and we do not have our own distribution facilities. Additionally, we do not intend to develop such facilities for any product in the near future. Instead, we contract with third parties for the manufacture, warehousing, order management, billing and collection and distribution of our products and product candidates. This virtual approach allows us the flexibility to adapt as our pipeline advances.

We expect to continue to rely solely on third-party manufacturers to manufacture drug substance and final drug products for both clinical development and commercial sale.

Cinryze

In conjunction with the Lev acquisition, we acquired a Distribution and Manufacturing Services Agreement with Sanquin, which was amended and restated in January 2010 as described above. Additionally, in January 2010, we entered into the ROW Agreement as described above.

Restated U.S. Agreement

The terms of the Restated US Agreement related to manufacturing provide that Sanquin shall manufacture Cinryze for us on a toll manufacturing basis, using plasma supplied by us, for a manufacturing fee. During the term, we shall purchase from Sanquin an annual minimum quantity of Cinryze established by the parties for such calendar year.

Sanquin is implementing structural and equipment changes to its Amsterdam and Brussels manufacturing facilities. We previously funded such changes to the Brussels manufacturing facility and a portion of such

changes to the Amsterdam manufacturing facility, each through a loan facility of an aggregate amount of €7,500,000 (approximately \$9.9 million). Pursuant to the Restated US Agreement, Sanquin will implement additional structural and equipment changes to the Brussels manufacturing facility, financed through an additional €5,000,000 (approximately \$6.6 million) loan facility provided by us. The €5,000,000 loan facility was satisfied during 2011 and Sanquin will repay the remaining loan amount by January 1, 2015 by providing us with a discount to the per unit purchase price of product.

Sanquin will use commercially reasonable efforts to obtain regulatory approval to manufacture Cinryze in the Amsterdam manufacturing facility prior to a date agreed to by the parties. Sanquin will enter into manufacturing agreements with one or more third party manufacturers, which may include affiliates of Sanquin, (reasonably acceptable to us) pursuant to which such third party manufacturers shall provide certain back-up manufacturing facilities for Cinryze. In the event that certain events occur which result in Sanquin permanently ceasing to manufacture Cinryze, Sanquin will grant us a perpetual license under its intellectual property related to Cinryze and assign to us each of the agreements with such third party manufacturers. In consideration thereof, we will pay a one-time fee to Sanquin as well as a royalty on future sales of Cinryze or any future C1-INH product.

ROW Agreement

The terms of the ROW Agreement related to manufacturing provide that Sanquin will manufacture Cinryze either based on a supply of plasma provided by Sanquin or on a toll-manufacturing basis using plasma supplied by us for a manufacturing fee. The manufacturing fee will be comprised of a base fee and a royalty which shall vary based upon the source of the plasma utilized. The parties will negotiate in good faith a new purchase price and manufacturing fee for any additional new products developed in accordance with the terms of the ROW Agreement. Beginning in 2015, we shall purchase at least a minimum quantity of Cinryze or future C1-INH product from Sanquin annually, which quantities shall be determined by the Joint Steering Committee in 2013.

Sanquin will enter into manufacturing agreements with one or more third party manufacturers, which may include affiliates of Sanquin, (reasonably acceptable to us) pursuant to which such third party manufacturers shall provide certain back-up manufacturing facilities for the products. In the event that certain events occur which result in Sanquin permanently ceasing to manufacture Cinryze or future C1-INH derived products, Sanquin will grant us a perpetual license under its intellectual property related to Cinryze or any future C1-INH product and assign to us each of the agreements with such third party manufacturers. In consideration thereof, we will pay a one-time fee to Sanquin as well as a royalty on future sales of Cinryze or any future C1-INH product.

Plasma

Cinryze is derived from human plasma sourced from commercial plasma suppliers. The sourcing of plasma, and the production of products derived from plasma, is regulated extensively by the FDA and other medical product and health care regulatory agencies. We rely on a combination of sources for plasma including (i) long term supply agreements, (ii) periodic "spot purchases" of plasma from third party plasma suppliers, and (iii) we have an option to acquire our own plasma centers.

Supply Agreement with DCI Management Group, LLC

In connection with our acquisition of Lev, we became party to a supply agreement for the purchase and sale of plasma with DCI Management Group, LLC pursuant to which we will purchase quantities of U.S. Source Plasma to be utilized in the production of product under our Distribution and Manufacturing Services Agreement with Sanquin Blood Supply Foundation. In July 2009 we amended the terms of the agreement. Under the amended agreement, the supplier agreed to sell us specified annual quantities of plasma in accordance with applicable good manufacturing practices. Our annual purchase commitment is estimated to range between approximately \$23 million and \$27 million for the balance of the term of the agreement. Our contractual purchase commitments are subject to annual percentage increases based on market conditions and do not include the cost of additional

pre-delivery testing which we may require the supplier to undertake. We estimate our remaining commitment under this agreement to be approximately \$100 million.

The amended agreement expires December 31, 2013, unless sooner terminated in accordance with its terms. Either party may terminate the agreement upon written notice if the other party is in material breach of any provision thereof, subject to applicable cure periods. Subject to the supplier's ability to mitigate damages, in the event we are in default of our payment obligation under the contract, we will be liable to purchase the minimum quantities of plasma specified under the contract for the balance of the term. Upon expiration of the agreement, or in the event the agreement is terminated for reasons other than as set forth above, we will be obligated to purchase a closing inventory of plasma in the quantity specified in the agreement.

In February 2010 we amended the agreement to extend the term to December 31, 2015. The amendment fixed the pricing of product for 2011. Beginning in 2012, the annual price adjustment shall depend on market conditions and increases or decreases shall be limited to the maximum percentage per year.

Intermediate Supply Agreement with Biotest AG

On June 19, 2009, we entered into an intermediate supply agreement (the "Supply Agreement") with Biotest AG ("Biotest") pursuant to which we will sell to Biotest all excess output of specific intermediate plasma products (the "Intermediates") derived from the plasma processed by Sanquin in manufacturing Cinryze. In addition, we offered Biotest a right of first refusal to purchase unprocessed plasma in the event we elect to sell unprocessed plasma to a third party. Biotest also agreed to provide us with a right of first refusal, subject to certain exceptions, to repurchase certain by products derived from the Intermediates. The Supply Agreement has an initial term expiring December 31, 2014, unless sooner terminated. In addition we established pricing for a pre-determined volume of source plasma (the "Target Volume"), provided that the parties shall renegotiate pricing terms upon achievement of the Target Volume. Either party may terminate the Supply Agreement upon written notice if the other party is in material breach of any provision thereof, subject to applicable cure periods. In the event of a breach of the Supply Agreement by Biotest, Biotest shall be liable to purchase all amounts of Intermediates deliverable under the Supply Agreement during its remaining term.

Strategic Supply Agreement with Biotest Pharmaceuticals Corporation

In February 2010 we entered into a Strategic Supply Agreement with Biotest Pharmaceuticals Corporation (BPC) pursuant to which we will purchase certain quantities of plasma. Our contractual purchase commitments are subject to annual percentage increases based on changes in the consumer price index and is subject to other market conditions. BPC has built three additional plasma centers to be dedicated to our plasma requirements during the term of the agreement. Such plasma centers shall receive regulatory approval for operations no later from 21, 27 and 29 months from the effective date of the agreement. Two of the centers have received regulatory approval. On or after December 31, 2012 we shall have a right but not the obligation, with twelve month prior notice, to purchase the three plasma centers at a pre-determined purchase price. The agreement expires December 31, 2015. We estimate our remaining commitment under this agreement to be approximately \$46 million.

ROW Agreement with Sanquin

As described above, we entered into the ROW Agreement with Sanquin on January 8, 2010. Under the terms of the ROW Agreement, Sanquin will manufacture Cinryze either based on a supply of plasma provided by Sanquin or on a toll-manufacturing basis using plasma supplied by us.

Vancocin

In December 2005 we entered into a toll manufacturing agreement with Norwich Pharmaceuticals, Inc. (NPI) (formerly OSG Norwich Pharmaceuticals, Inc.) to produce finished Vancocin product. The qualification process

required to transfer Vancocin manufacturing from Lilly to NPI was completed in February 2006. All approvals were finalized in the second quarter of 2006 and, since June 30, 2006, all of our finished product has been supplied from NPI. In April 2011, we amended the agreement to extend the term to August 31, 2016. The amendment fixed the pricing of product for the remainder of 2011 and the full year 2012.

In April 2006, we also entered into an agreement with Alpharma, Inc. for the manufacturing of API for Vancocin. In October, 2007, we amended this agreement with Alpharma to extend the agreement until December 2011 and identified an additional production facility from which we began to acquire API during 2010. In January 2011 we extended our agreement with Xellia Pharmaceuticals, Inc. (formerly Alpharma Inc.) through December 2015.

We require in our manufacturing and processing agreements that all third-party contract manufacturers and processors produce drug substance and product in accordance with the FDA's current Good Manufacturing Practices and all other applicable laws and regulations. We maintain confidentiality agreements with potential and existing manufacturers in order to protect our proprietary rights related to our marketed drug and drug candidates.

Customers

We have principally sold our products directly to wholesale drug distributors and specialty pharmacies/ specialty distributors in the United States who then distribute the product to pharmacies, hospitals, patients, physicians and long-term care facilities, among others. In the fourth quarter of 2011, we have also begun to sell product to drug distributors in Europe who then distribute the product to pharmacies, hospitals, and physicians.

Net product sales to customers who accounted for 10% or more of our net product sales during the years ended December 31, 2011, 2010 and 2009 are as follows:

	Percentage of total revenues		
	2011	2010	2009
Customer A	27%	25%	29%
Customer B	24%	24%	25%
Customer C	20%	21%	13%
Customer D	17%	16%	12%
Customer E	—	10%	—
Total	<u>88%</u>	<u>96%</u>	<u>79%</u>

In 2011, four customers represented approximately 88% of our total net product sales. We do not believe that the loss of any one of these customers would have a material adverse effect on product sales because product sales would shift to other customers or alternative forms of distribution. However, the loss of a customer could increase our dependence on a reduced number of customers. We have entered into distribution service agreements with the parties identified in the table above.

Marketing and Sales

Our initial sales organization was established in 2008 in the Northeastern U.S. to target doctors and hospitals to promote Vancocin. With the commercial launch of Cinryze, we have transitioned our existing sales force and expanded our sales force to target doctors who treat patients who have been diagnosed with HAE. Given the relatively limited HAE patient population, our U.S. sales force is small compared to other drugs with similar gross revenues. Our sales force primarily focuses its efforts towards allergists, immunologists, gastroenterologists and home healthcare providers.

In 2010 we established a sales organization in Europe, initially focusing on Germany and the UK. The aim of this effort was to target key healthcare professionals in preparation for the launches of Cinryze and Buccolam. During 2011 the sales team expanded to cover both new European geography's and to meet the specific needs of our customers. Today the primary focus of the sales teams is allergists, immunologists, neurology and pediatricians. We also support a wider group of healthcare professional to deliver care at home and training support for patients, parents and care givers.

Foreign Operations

We conduct business in European countries through wholly-owned subsidiaries. Our international businesses are subject to risks customarily encountered in foreign operations, including fluctuations in foreign currency exchange rates and controls, import and export controls and other economic, political and regulatory policies of local governments. We currently have operations in Belgium, Canada, France, Italy, Germany, Spain, Switzerland and the United Kingdom. In anticipation of our commercial sales launch of Cinryze, Buccolam and Plenadren in Europe and certain other countries, we have begun to expand our own commercial organizations in such territories in order to market and sell Cinryze, Buccolam and Plenadren through our own sales force in these territories. Outside of the United States and European territories, we will evaluate sales efforts on a country-by-country basis, and it is possible that we will rely on relationships with one or more companies with established distribution systems and direct sales forces in such countries.

Patents and Proprietary Technology

We believe that patent protection and trade secret protection are important to our business and that our future will depend, in part, on our ability to maintain our technology licenses, maintain trade secret protection, obtain patents and operate without infringing the proprietary rights of others both in the U.S. and abroad. The last core patent protecting Vancocin expired in 1996. We own three pending U.S. patent applications covering vancomycin related technology. In order to continue to obtain commercial benefits from Vancocin, we will rely on product manufacturing trade secrets, know-how and related non-patent intellectual property, and regulatory barriers to competitive products. There are no core patents protecting Cinryze. There are no core patents protecting Buccolam. We own, through a subsidiary, 1 non-U.S. issued patent and two pending U.S. patent applications covering technology related to glucocorticoid therapy. We have three pending U.S. patent applications covering benzimidazole related technology. We also file international, regional and non-U.S. national patent applications as appropriate in order to pursue patent protection in major foreign countries.

As patent applications in the U.S. are maintained in secrecy until patents are issued (unless earlier publication is required under applicable law or in connection with patents filed under the PCT) and as publication of discoveries in the scientific or patent literature often lags behind the actual discoveries, we cannot be certain that we or our licensors were the first to make the inventions described in each of these pending patent applications or that we or our licensors were the first to file patent applications for such inventions. Furthermore, the patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions, and, therefore, the breadth of claims allowed in biotechnology and pharmaceutical patents or their enforceability cannot be predicted. We cannot be sure that any patents will issue from any of these patent applications or, should any patents issue, that we will be provided with adequate protection against potentially competitive products. Furthermore, we cannot be sure that should patents issue, they will be of commercial value to us, or that private parties, including competitors, will not successfully challenge these patents or circumvent our patent position in the U.S. or abroad. In the absence of adequate patent protection, our business may be adversely affected by competitors who develop comparable technology or products.

Pursuant to the terms of the Uruguay Round Agreements Act, patents filed on or after June 8, 1995 have a term of twenty years from the date of filing, irrespective of the period of time it may take for the patent to ultimately issue. This may shorten the period of patent protection afforded to our products as patent applications in the biopharmaceutical sector often take considerable time to issue. Under the Drug Price Competition and Patent

Term Restoration Act of 1984, a sponsor may obtain marketing exclusivity for a period of time following FDA approval of certain drug applications, regardless of patent status, if the drug is a new chemical entity or if new clinical studies were used to support the marketing application for the drug. Pursuant to the FDA Modernization Act of 1997, this period of exclusivity can be extended if the applicant performs certain studies in pediatric patients. This marketing exclusivity prevents a third party from obtaining FDA approval for a similar or identical drug under an Abbreviated New Drug Application or a “505(b)(2)” New Drug Application.

The Drug Price Competition and Patent Term Restoration Act of 1984 also allows a patent owner to obtain an extension of applicable patent terms for a period equal to one-half the period of time elapsed between the filing of an Investigational New Drug Application, or IND, and the filing of the corresponding New Drug Application, or NDA, plus the period of time between the filing of the NDA and FDA approval, with a five year maximum patent extension. We cannot be sure that we will be able to take advantage of either the patent term extension or marketing exclusivity provisions of this law.

In order to protect the confidentiality of our technology, including trade secrets and know-how and other proprietary technical and business information, we require all of our employees, consultants, advisors and collaborators to enter into confidentiality agreements that prohibit the use or disclosure of confidential information. The agreements also oblige our employees, and to the extent practicable, our consultants, advisors and collaborators, to assign to us ideas, developments, discoveries and inventions made by such persons in connection with their work with us. We cannot be sure that these agreements will maintain confidentiality, will prevent disclosure, or will protect our proprietary information or intellectual property, or that others will not independently develop substantially equivalent proprietary information or intellectual property.

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success depends, in part, on our ability to develop and maintain a strong patent position for our products and technologies in clinical development, both in the U.S. and in other countries. Litigation or other legal proceedings may be necessary to defend against claims of infringement, to enforce our patents, or to protect our trade secrets, and could result in substantial cost to us and diversion of our efforts. We intend to file applications as appropriate for patents describing the composition of matter of our drug candidates, the proprietary processes for producing such compositions, and the uses of our products and drug candidates.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements on the clinical development, licensure, manufacture, distribution and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, processing, quality control, safety, effectiveness, labeling, packaging, storage, handling, distribution, record keeping, approval, advertising, marketing, and promotion of our products. All of our products will require FDA regulatory approval before commercialization. In particular, therapeutic products for human use are subject to rigorous preclinical and clinical testing and other requirements of the Federal Food, Drug, and Cosmetic Act, and in the case of biological products the Public Health Service Act, each implemented by the FDA, as well as similar statutory and regulatory requirements of foreign countries. Obtaining these marketing approvals and subsequently complying with ongoing statutory and regulatory requirements is costly and time consuming. Any failure by us or our collaborators, licensors or licensees to obtain or maintain, or any delay in obtaining, regulatory approval or in complying with other requirements, could adversely affect the commercialization of products then being developed by us and our ability to receive product or royalty revenues.

The steps required before a new drug product may be distributed commercially in the U.S. generally include:

- conducting appropriate preclinical laboratory evaluations of the product’s chemistry, formulation and stability, and animal studies to assess the potential safety and efficacy of the product;

- submission to the FDA of an Investigational New Drug Application, including the results of preclinical evaluations and tests, along with manufacturing information and analytical data plus any clinical data if the product previously was administered to humans including outside the US;
- obtaining approval of Institutional Review Boards, or IRBs, to introduce the drug into humans in clinical studies;
- conducting adequate and well-controlled human clinical trials that establish the safety and efficacy of the drug product candidate for the intended use, typically in the following three sequential, or slightly overlapping stages:
 - Phase 1: The drug is initially introduced into healthy human subjects or patients and tested for safety, dose tolerance, absorption, metabolism, distribution, excretion and evidence of biological activity;
 - Phase 2: The drug is studied in controlled, exploratory therapeutic trials in a limited number of patients to identify possible adverse effects and safety risks, to determine dose tolerance and the optimal effective dosage, and to collect initial efficacy data of the product for specific targeted diseases or medical conditions;
 - Phase 3: The drug is studied in an expanded, adequate, well-controlled patient population at multiple clinical study sites to demonstrate efficacy and safety, and in the case of a biological product also purity and potency, at the optimized dose by measuring a primary endpoint established at the outset of the study;
- submitting the results of basic research, including pharmacology and mechanisms of action animal studies, and clinical studies as well as chemistry, manufacturing and controls information and patent information on the drug to the FDA in a NDA or BLA;
- undergoing a successful FDA pre-approval inspection prior to approval of an NDA or BLA; and
- obtaining FDA approval of the NDA or BLA with accompanying labeling prior to any commercial sale or shipment of the drug or biologic product.

This process generally takes a number of years and typically requires substantial financial resources, and we cannot be certain that any approval will be granted on a timely or commercially viable basis, if at all. The results of preclinical studies and initial clinical trials are not necessarily predictive of the results from large-scale clinical trials, and all clinical trials may be subject to additional costs, delays or modifications due to a number of factors, including the difficulty in obtaining enough patients, clinical investigators, drug supply, or financial support, or because of unforeseen adverse effects or efficacy issues. In addition, an independent IRB at each clinical site proposing to conduct the clinical trials must review and approve each study protocol and oversee the conduct of the trial. The FDA may also raise questions about the conduct of the trials as outlined in the IND and impose a clinical hold on the trial. If a clinical hold is imposed, all of FDA's concerns must be resolved before the trial may begin again. Some studies also use a special committee often referred to as a data safety monitoring board to review data from the study as it progresses and determine whether it is appropriate for the study to continue.

Preclinical and clinical studies take several years to complete, and there is no guarantee that an IND we submit will result in a submission of an NDA or BLA within any specific time period, if at all. Similar risks and uncertainties apply to the conduct and approval for licensure and marketing a product in non-U.S. markets around the world.

The FDA has issued regulations intended to expedite the approval process for the development, evaluation and marketing of new therapeutic products intended to treat life-threatening or severely debilitating diseases, especially where no alternative therapies exist. If applicable, these provisions may streamline the traditional product development process in the U.S. Similarly, products that represent a substantial improvement over existing therapies may be eligible for priority review and a FDA expedited review time of six months. Nonetheless, even if a product is eligible for these programs, or for priority review, approval may be denied or

delayed by the FDA or additional trials may be required. As a condition of approval FDA also can require further testing of the product and monitoring of the effect of commercialized products, restrict the approved conditions of use in the product labeling, or impose other limitations or requirements such as in a Risk Evaluation and Mitigation Strategy (REMS) requirement. The limitations on approval can include restricted access to the product and potential registries in the US and to a greater extent in Europe., In addition, all new products are subject to requirements to assess pediatric safety and effectiveness, unless a waiver or deferral is obtained. The Agency has the power to prevent or limit further marketing of a product based on the results of these post-approval commitments. Upon approval, a drug or biologic product may be marketed only in those dosage forms and for those uses approved in the NDA or BLA.

Any products manufactured or distributed by us pursuant to FDA approval are subject to extensive continuing post-approval regulation by the FDA, including record-keeping requirements, obligations to investigate, analyze and report adverse experiences, other reporting requirements and restrictions on advertising and promotional activities. In addition to continued compliance with standard regulatory requirements, the FDA also may require post-marketing testing and surveillance to monitor the safety and efficacy of the marketed product. Results of post-marketing studies may limit or expand the further marketing of the products. If we propose any modifications to a product, including changes in indication, manufacturing process, manufacturing facility or labeling, we may need to submit a NDA or BLA supplement to the FDA, and will not be able to commercialize any product with these modifications until FDA approval is received. Product approvals may be withdrawn or limited if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product are discovered following approval.

An abbreviated approval process is currently available under the Federal Food, Drug and Cosmetic Act (FDCA) for generic versions of conventional chemical drug products, sometimes referred to as small molecule drugs. The applicant for a generic version of a small molecule drug must refer to an approved drug for which full clinical data demonstrating safety and effectiveness were submitted (the “reference drug”). Generally, the generic applicant must show that its product has the same active ingredients, dosage form, strength, route of administration, and labeling as the reference drug, and is absorbed in the body at the same rate and to the same extent as the referenced drug. It is possible to obtain permission to deviate from some of these requirements. A generic applicant must seek approval for conditions of use for which FDA approved the reference drug, it must include certifications to patents listed with FDA for the reference drug, and it must wait for the expiry of any applicable non-patent exclusivity in order to receive final approval, unless the exclusivity is associated with a condition of use that the generic applicant is permitted to omit for its product. A generic applicant must also manufacture its product in accordance with current good manufacturing practices and other product quality standards. FDA also permits abbreviated applications that cite to reference drugs and propose new conditions of use or other changes that require clinical data. For these applications, FDA may require substantially less data and information than it requires for reference drugs. These abbreviated approval processes could have a material impact on our business as generic products that compete with our products may be significantly less costly to bring to market and may be priced significantly lower than our products.

An abbreviated approval process is also available under the Public Health Service Act (PHSA) for biosimilar versions of biologics licensed under full BLAs (“reference biologics”). A biosimilar applicant generally must submit analytical, animal, and clinical data showing that the proposed product is “highly similar” to the reference product and has no “clinically meaningful differences” from the reference product in terms of the safety, purity, and potency, although FDA may waive some or all of these requirements. The proposed product also must have the same route of administration, dosage form, strength, and mechanism(s) of action (if known) as the reference biologic, and the application must seek approval for a condition of use for which FDA already approved the reference biologic. FDA cannot license a biosimilar until 12 years after it first licensed the reference biologic. After expiry of the applicable exclusivity, our biologics may face direct competition from licensed biosimilar products. Biosimilar manufacturers may price these products at material discounts to our products. Therefore, this competition could have a negative effect on sales and gross profits for our product, and on our overall profitability and financial condition.

In addition to obtaining FDA approval for each indication for which we plan to market product, each drug or biologic product manufacturing establishment must register with the FDA, list its drug products with the FDA, comply with current Good Manufacturing Practices (cGMPs) and undergo periodic inspections by the FDA.

In complying with the FDA's cGMP regulations, manufacturers must continue to spend time, money and effort on facilities and equipment, process control, recordkeeping, personnel training, quality control validation, and auditing to ensure that the marketed product meets applicable specifications and other requirements. The FDA periodically inspects drug or biologic product manufacturing facilities to ensure compliance with cGMPs. Failure to comply with FDA requirements, including cGMPs, subjects the manufacturer to possible FDA enforcement action, such as untitled letters, Warning Letters, suspension of manufacturing operations, seizure of the product, voluntary or mandatory recall of a product, injunctive action, consent decrees and/or suspension or revocation of product approval, as well as possible civil and criminal penalties. We currently rely on, and intend to continue to rely on, third parties to manufacture our compounds and products. Such third parties will be required to comply with FDA requirements, including cGMPs. We cannot be certain that we, or our present or future suppliers or third-party manufacturers, will be able to comply with all FDA regulatory requirements, and potential consequences of non-compliance could have a material adverse impact on our business.

Products manufactured in the U.S. for distribution abroad will be subject to FDA regulations regarding export, as well as the requirements of the country to which they are shipped. These latter requirements are likely to cover the conduct of clinical trials, the submission of marketing applications and all aspects of product manufacture and marketing. Such requirements can vary significantly from country to country. As part of possible strategic relationships, our collaborators may be responsible for the foreign regulatory approval process of our products, although we may be legally liable for noncompliance. Foreign establishments manufacturing drug or biologic products for distribution in the U.S. also must register their establishments and list their products with the FDA, and comply with cGMPs. They also are subject to periodic inspection by the FDA or by local authorities under agreement with the FDA.

The FDA's laws, regulations and policies may change, and additional governmental regulations or requirements may be enacted that could delay, limit or restrict, or prevent regulatory approval of our products or affect our ability to test, manufacture, market, or distribute our products following approval.

In December 2003, the Medicare Prescription Drug, Improvement and Modernization Act (MMA) was signed into law. The MMA provides outpatient prescription drug coverage to eligible Medicare beneficiaries. The primary prescription drug benefit under the MMA, the Medicare Part D coverage, began in January 2006. The new Part D prescription drug benefit is administered regionally through Medicare-approved insurance plans. The legislation allows for the importation of prescription drugs from Canada, but only if the Secretary of the U.S. Department of Health and Human Services certifies to Congress that such importation would pose no additional risk to the public's health and safety and would result in significant reduction in the cost to customers, which the Secretary thus far has not done. There can be no assurance that this certification requirement will be maintained in future legislation or that the certification will continue to be withheld. The impact of this program could be negative over the intermediate and longer term for our business generally as greater federal involvement and budget constraints may increase the likelihood of additional pricing pressures or controls in the future.

In March 2010, the Patient Protection and Affordable Care Act (PPACA) was signed into law and was subsequently amended by the Health Care and Education Reconciliation Act of 2010. The PPACA, as amended, is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. Several provisions of the new law, which have varying effective dates, will affect us. These include new requirements on private insurance companies that prohibit coverage denials because of a pre-existing condition; prohibit the application of annual and lifetime benefits limits on health insurance policies; and prohibit coverage rescissions (except for fraud) and health-based insurance rating. In addition, the PPACA, as amended, funds an interim high risk pool that states can draw on. Following the expiration of this high risk pool funding,

the PPACA provides for the creation of state-run “exchanges” that will allow people without employer-provided coverage, or who cannot afford their employer’s plan, to buy health insurance. The PPACA will also provide federal subsidies to those who cannot afford premiums. Collectively, these factors may increase the availability of insurance reimbursement to patients seeking the products that ViroPharma commercializes. However, PPACA’s amendments to the Social Security Act will likely increase certain of our costs. For example, an increase in the Medicaid rebate rate from 15.1% to 23.1% was effective as of January 1, 2010, and the volume of rebated drugs has been expanded to include beneficiaries in Medicaid managed care organizations, effective as of March 23, 2010. As of 2011, the PPACA also imposes a manufacturer’s fee based on the sale of branded Pharmaceuticals (excluding orphan drugs) to specified government programs, expands the 340B drug discount program (excluding orphan drugs), and includes a 50% discount (funded by the drug manufacturer) on brand name drugs for Medicare Part D participants in the coverage gap, or “doughnut hole”. The PPACA will have immediate effects on our business and we will also continue to monitor the trends and changes that may be encouraged by the legislation that may potentially impact on our business over time.

Federal and state governments also have pursued direct methods to reduce the cost of drugs for which they pay. We participate in state government-managed Medicaid programs as well as certain other qualifying federal and state government programs whereby discounts and mandatory rebates are provided to participating state and local government entities. We also participate in other programs with government entities, the most significant of which are the U.S. Department of Defense and the U.S. Department of Veterans Affairs. These entities receive minimum discounts based off a defined “non-federal average manufacturer price” for purchases. Additional programs in which we participate provide mandatory discounts for outpatient medicines purchased by certain Public Health Service entities and “disproportionate share” hospitals (hospitals meeting certain criteria regarding the percentage of needy population served).

In connection with several of these government programs, we are required to report prices to various government agencies. Pricing calculations vary among programs. The calculations are complex and are often subject to interpretation by the reporting entities, government agencies and the courts. Our methodologies for calculating these prices could be challenged under false claims laws or other laws. We could make a mistake in calculating reported prices and required discounts, which could result in retroactive liability to government agencies. Government agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. If we make these mistakes or if governmental agencies make these changes, we could face, in addition to prosecution under federal and state false claims laws, substantial liability and civil monetary penalties, exclusion of our products from reimbursement under government programs, criminal fines or imprisonment, or prosecutors may impose a Corporate Integrity Agreement, Deferred Prosecution Agreement, or similar arrangement.

Our operations are also subject to federal and state anti-kickback laws. Certain provisions of the Social Security Act prohibit entities such as us from knowingly and willfully offering, paying, soliciting or receiving any form of remuneration (including any kickbacks, bribe or rebate) in return for the referral of items or services for which payment may be made under a federal health care program, or in return for the recommendation, arrangement, purchase, lease or order of items or services for which payment may be made under a federal health care program. Violation of the federal anti-kickback law is a felony, punishable by criminal fines and imprisonment for up to five years or both. In addition, the Department of Health and Human Services may impose civil penalties and exclude violators from participation in federal health care programs such as Medicare and Medicaid. Many states have adopted similar prohibitions against payments intended to induce referrals of products or services paid by Medicaid or other third party payors. Several states have also enacted laws requiring recordkeeping, compliance requirements, and reporting of gifts and other value given to healthcare providers. Under the PPACA, beginning in March 2013, pharmaceutical manufacturers will be required to report payments or other transfers of value made to healthcare providers during the preceding calendar year. These reports will be placed on a public database. Similarly, beginning in April 2012, pharmaceutical manufacturers will be required to report samples of prescription drugs requested by and distributed to healthcare providers during the preceding calendar year. The PPACA does not state whether the sample reports will be made publicly available. Because of

the far-reaching nature of these laws, there can be no assurance that the occurrence of one or more violations of these laws would not result in a material adverse effect on our business, financial condition and results of operations.

Moreover, we anticipate that Congress, state legislatures and the private sector will continue to review and assess controls on health care spending. Any such proposed or actual changes could cause us or our collaborators to limit or eliminate spending on development projects and may otherwise affect us. We cannot predict the likelihood, nature, or extent of adverse governmental regulation that might result from future legislative or administrative action, either in the U.S. or abroad. Additionally, in both domestic and foreign markets, sales of our proposed products will depend, in part, upon the availability of reimbursement from third-party payors, such as government health administration authorities, managed care providers, private health insurers and other organizations. Significant uncertainty often exists as to the reimbursement status of newly approved health care products. In addition, third-party payors are increasingly challenging the price and cost effectiveness of medical products and services. There can be no assurance that our proposed products will be considered cost-effective or that adequate third-party reimbursement will be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product research and development.

In the United States, the Orphan Drug Act provides incentives to drug manufacturers to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that affect fewer than 200,000 individuals in the United States, or for a disease that affects more than 200,000 individuals in the United States, where the sponsor does not realistically anticipate its product becoming profitable. The FDA has granted Cinryze seven years of marketing exclusivity to Cinryze (C1 esterase inhibitor [human]) for routine prophylaxis in adolescent and adult patients with hereditary angioedema (HAE) pursuant to the Orphan Drug Act. Lev originally received orphan drug designation for Cinryze by the Office of Orphan Products Development on July 16, 2004. Under the Orphan Drug Act, a manufacturer of a designated orphan product can seek certain tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for that product for the orphan indication. While the marketing exclusivity of an orphan drug would prevent other sponsors from obtaining approval of the same drug compound for the same indication unless the subsequent sponsors could demonstrate clinical superiority or a market shortage occurs, it would not prevent other sponsors from obtaining approval of the same compound for other indications or the use of other types of drugs for the same use as the orphan drug. The U.S. Congress has considered, and may consider in the future, legislation that would restrict the duration or scope of the market exclusivity of an orphan drug and, thus, we cannot be sure that the benefits of the existing statute will remain in effect. Additionally, we cannot be sure that other governmental regulations applicable to our products will not change. We rely on the marketing exclusivity provided by the Orphan Drug Act for Cinryze as there are no core patents protecting Cinryze.

We are also subject to various other federal, state and local laws, rules, regulations and policies relating to safe working conditions, clinical, laboratory and manufacturing practices, environmental protection, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, previously used in connection with our research work. Although we believe that our safety procedures for handling and disposing of such materials comply with current federal, state and local laws, rules, regulations and policies, the risk of accidental injury or contamination from these materials cannot be entirely eliminated. We may also incur significant costs to comply with such laws and regulations now and in the future, and the failure to comply may have a material adverse impact on our business.

Foreign Regulation

In addition to regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials and marketing approval for drugs. The foreign regulatory approval process includes all of the risks associated with FDA approval set forth above, as well as additional country-specific regulations. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the

product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

For example, under European Union regulatory systems, we may submit marketing authorizations either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states, and is required for certain categories of products including biological products. The decentralized procedure provides for mutual recognition of national approval decisions, and the holder of a national marketing authorization may submit an application to the remaining member states. We submitted our Marketing Authorization Application for Cinryze for the acute treatment and prophylaxis of HAE to the European Medicines Agency (EMA), using the centralized procedure.

Before submitting a Marketing Authorization Application (MAA) in the EU, a company must obtain approval of a Paediatric Investigation Plan (PIP) from the EMA's Paediatric Committee (PDCO). The PIP describes the pediatric development of a product and may include pharmaceutical development, non-clinical and clinical activities. The PIP will also define the age ranges of the children for whom the product must be developed and the timelines that the sponsor must meet, including, for example, the deferral of some studies. The PIP is updated as new information is obtained. The incentives for completing the PIP include 6 months patent extension and, for orphan medicinal products, an additional 2 years orphan exclusivity. In October 2009 a PIP was approved for Cinryze.

Legislation similar to the Orphan Drug Act has been enacted in other countries outside of the United States, including the European Union. The orphan legislation in the European Union is available for therapies addressing conditions that affect five or fewer out of 10,000 persons. The market exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product is sufficiently profitable not to justify maintenance of market exclusivity. In October 2009 and December 2007, the Company was granted orphan medical product designation for Cinryze and maribavir, respectively, by the Committee for Orphan Medicinal Products of the EMA. In addition, the EMA must reconfirm the orphan designation in connection with the approval of an MAA.

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. A member state may approve a specific price or level of reimbursement for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In the event we receive regulatory approval of Cinryze in the EU, we will need to engage with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required in each country.

Competition

Other companies are developing treatments for the disease states for which we market products or are developing product candidates, including compounds in preclinical and clinical development for HAE and *C. difficile*. These companies include both public and private entities, including well-known, large pharmaceutical companies, chemical companies, biotechnology companies and research institutions. Our ability to compete successfully will be based on our ability to:

- develop proprietary products;
- attract and retain scientific personnel;
- obtain patent or other protection for our products;

- obtain required regulatory approvals; and
- manufacture and successfully market our products either alone or through outside parties.

HAE

We do not have patent protection for the composition of Cinryze and we rely on the exclusivity provided by the Orphan Drug Act. The FDA granted Cinryze seven years of marketing exclusivity to Cinryze C1 inhibitor (human) for routine prophylaxis of HAE pursuant to the Orphan Drug Act. Steroid based products are currently used for prophylaxis of HAE.

In the fourth quarter of 2009 the FDA granted marketing approval of CSL Behring's product, Berinert® C1-Esterase Inhibitor, Human, for the treatment of acute abdominal or facial attacks of hereditary angioedema and Berinert has received exclusivity pursuant to the Orphan Drug Act. This approval will prevent us from obtaining FDA licensure and marketing our C1-INH product for the treatment of acute abdominal or facial attacks HAE for up to seven years. In January 2012, the FDA approved a label expansion for self-administration of Berinert. As part of the label expansion, Berinert is now also indicated to treat life-threatening laryngeal HAE attacks, as well as facial and abdominal attacks.

In August 2011, the FDA granted Shire plc a marketing approval for FIRAZYR® (icatibant injection) for the self-administered treatment of acute attacks of HAE in adults 18 years of age and older.

In the fourth quarter of 2009, Dyax received approval for their product candidate for the acute treatment of HAE.

Clostridium Difficile-Associated Diarrhea (CDAD)

The last core patent protecting Vancocin expired in 1996. As a result, there is a potential for significant competition from generic versions of Vancocin. Such competition would result in a significant reduction in sales of Vancocin. We believe that our three year exclusivity associated with our recently approved supplemental New Drug Application, other regulatory hurdles (notwithstanding the actions taken by the OGD, described below), as well as product manufacturing trade secrets, know-how and related non-patent intellectual property may impact market entry of generic competition. However, there can be no assurance that these barriers will actually impact generic competition.

In December 2008, FDA changed OGD's 2006 bioequivalence recommendation, which we have opposed since its original proposal in March 2006, by issuing draft guidance for establishing bioequivalence to Vancocin which would require generic products that have the same inactive ingredients in the same quantities as Vancocin ("Q1 and Q2 the same"), and that meet certain other conditions, to demonstrate bioequivalence through comparative in vitro dissolution testing. Under this latest proposed method, any generic product that is not Q1 and Q2 the same as Vancocin would need to conduct an in vivo study with clinical endpoints to demonstrate bioequivalence with Vancocin. On August 4, 2009 the FDA's Pharmaceutical Science and Clinical Pharmacology Advisory Committee voted in favor of the OGD's 2008 draft guidelines on bioequivalence for Vancocin.

On December 14, 2011, we announced the modernization of labeling for Vancocin Capsules made effective through the FDA's approval of a supplemental new drug application (sNDA).

Through the sNDA approval, Vancocin's label for the first time includes clinical safety and efficacy data for the use of Vancocin capsules in treating *Clostridium difficile*. Vancocin's labeling now reflects safety and efficacy data from 260 patients with *C. difficile*-associated diarrhea (CDAD) treated with Vancocin in two pivotal studies of Genzyme Corporation's investigational drug, tolevamer. We purchased exclusive rights to the two studies from Genzyme for which we will pay Genzyme royalties of 10 percent, 10 percent and 16 percent on net sales of Vancocin for the three year period following the approval of the sNDA.

As a result of the sNDA approval, we believe Vancocin meets the requirements for three years of exclusivity, and that generic vancomycin capsules will not be approved during this period. Under FDA's regulations, labeling changes based on new clinical investigations that are essential to approval of the sNDA and to which the applicant has exclusive rights may be entitled to three years of exclusivity, and generic drug labeling cannot include information protected by such three-year exclusivity. A generic may seek approval by omitting labeling protected by three-year exclusivity; however, if such omissions render the generic drug less safe or effective, it cannot be approved until the three-year exclusivity expires.

We believe that attempting to omit Vancocin labeling changes protected by exclusivity would render generic versions of Vancocin less safe and effective. However, ultimately, the decision on a grant of three-year exclusivity and its effect on generic vancomycin capsule approvals resides with the FDA.

If FDA's proposed bioequivalence method for Vancocin becomes effective, and either FDA does not agree that our labeling changes made effective through our sNDA warrant exclusivity, or FDA acknowledges such exclusivity but nonetheless determines that generic products would be no less safe or effective in the absence of such labeling changes, then the time period in which a generic competitor could be approved would be reduced and multiple generics may enter the market. The approval of generic copies of Vancocin would materially impact our operating results, cash flows and possibly intangible asset valuations. This could also result in a reduction to the useful life of the Vancocin-related intangible assets. Management currently believes there are no indicators that would require a change in useful life as management believes that Vancocin will continue to be utilized along with generics that may enter the market, and the number of generics and the timing of their market entry is unknown.

In May 2011, FDA approved Optimer Pharmaceuticals' product, Difucid® (fidaxomicin), for the treatment of CDAD. Additionally, several other companies, including, Merck & Co., Sanofi-Aventis and Cubist Pharmaceuticals have clinical development programs with therapeutic agents for the treatment of *C. difficile* infection that could be found to have competitive advantages over Vancocin.

Approval of new products, or expanded use of currently available products, to treat CDAD, and particularly severe disease caused by *C. difficile* infection, could materially and adversely affect our sales of Vancocin. The number of units sold of Vancocin for the treatment of *C. difficile-associated diarrhea* has increased over the past 12 months but Vancocin's share of the U.S. market for this indication may decrease due to competitive forces and market dynamics. Metronidazole, a generic product, is regularly prescribed to treat CDAD at costs which are substantially lower than for Vancocin. In addition, products which are currently marketed for other indications by other companies may also be prescribed to treat this indication.

Buccolam

Buccolam is oromucosal midazolam provided in an individual dose formulation for buccal delivery. It is provided as a convenient, portable, ready to use, pre-filled oral syringe containing an age-specific dose. Buccolam is approved throughout the European Union and the EEA for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from three months to less than 18 years of age. Buccolam must only be used by parents/carers where the patient has been diagnosed to have epilepsy.

The licensing and availability of Buccolam follows its recent central approval in the European Union through the Pediatric Use Marketing Authorization (PUMA) in 2011. Buccolam is the first product approved using a PUMA, which is a type of centralized marketing authorization procedure requested for medicines already authorized but no longer covered by intellectual property rights and exclusively developed for use in children

In most European markets the key competitors for Buccolam are typically either available generically or are used off label.

There are a number of potential future competitors in the same or similar medical areas. Namely, the following are in Phase 3 trials in the U.S.: Intranasal midazolam (USL261 (ITI-111)) under development by Upsher-Smith Laboratories; intra muscular diazepam (Vanquix) being developed Pfizer; and, intra muscular midazolam from the University of Michigan. Also, DZNS nasal spray midazolam being developed by Acorda is in Phase 2 in the U.S.

Additionally, there are other potential products in early stage clinical development such as NRL-01 nasal diazepam developed by Neurelis and a unit dosed nasal spray midazolam developed by Medir

AI

In October 2011, we announced that we had entered into a definitive agreement to acquire The Swedish specialty pharmaceutical company, DuoCort Pharma, whose product, Plenadren® (hydrocortisone, modified release tablet), is an EU approved orphan drug for treatment of adrenal insufficiency (AI) in adults.

Plenadren is a dual release hydrocortisone replacement therapy designed to better mimic the normal physiological cortisol profile in order to improve outcomes for patients suffering from adrenal insufficiency. Plenadren is given as an oral tablet once daily. It has an outer layer releasing hydrocortisone immediately and an inner core releasing the rest of the drug more slowly during the day.

Adrenal Insufficiency is an orphan disorder that is caused by a dysfunction of the adrenal gland resulting in low levels of the corticoid hormone cortisol, which follows a circadian rhythm and regulates many critical body functions. Primary AI is referred to as Addison's disease and affects up to 15 in every 100,000 people worldwide. The most common symptoms of Addison's disease include fatigue, lightheadedness, muscle weakness, fever, weight loss, difficulty standing, anxiety, GI involvement and personality changes. Addison's disease also can be deadly. Complete depletion of cortisol leads to a life-threatening Addison's Crisis. To maintain a reasonable quality of life, these patients rely on cortisol replacement therapy. Because it is a chronic condition, these patients require this therapy throughout their entire lives.

Glucocorticoid hormone replacement therapy for adrenal insufficiency has been available for decades. However, studies have recorded complications and comorbidities including premature death, impaired quality of life, increased risk of cardiovascular diseases, and decreased bone mineral density in treated patients, most likely because it is difficult to match the natural secretion pattern of cortisol. We also are aware of at least one other program sponsored by Diurnal Pharma, a company based on the UK, that reported early stage clinical testing of a modified release hydrocortisone formulation for the treatment of adrenal insufficiency.

Employees

As of December 31, 2011, we had 311 employees, of which, 229 were employed in the United States and 82 were located in Europe. A significant number of our management and professional employees have had prior experience with pharmaceutical, biotechnology or medical products companies. None of our employees are covered by collective bargaining agreements. We believe that we have been successful in attracting skilled and experienced personnel; however, competition for such personnel is intense. We believe that our relations with our employees are good.

Executive Officers

<u>Name</u>	<u>Age</u>	<u>Position</u>
Vincent J. Milano	48	President, Chief Executive Officer and Chairman of the Board of Directors
Charles A. Rowland, Jr.	53	Vice President, Chief Financial Officer
Colin Broom, M.D.	56	Vice President, Chief Scientific Officer
Thomas F. Doyle	51	Vice President, Strategic Initiatives
Daniel B. Soland	53	Vice President, Chief Operating Officer
Robert G. Pietrusko	63	Vice President, Regulatory Affairs and Quality
J. Peter Wolf	42	Vice President, General Counsel and Secretary
Robert C. Fletcher	49	Vice President, Business Development and Project Management
Richard S. Morris	38	Vice President, Chief Accounting Officer

Vincent J. Milano joined the company in 1996, and has served as President and Chief Executive Officer since March 31, 2008. He became Chairman of the Board of Directors in December 2008. He served as our Chief Operating Officer from January 2006 to March 2008 and as Vice President, Chief Financial Officer of ViroPharma from November 1997 to March 2008. Mr. Milano has also previously served as our Vice President, Finance & Administration, as Treasurer, and as Executive Director, Finance & Administration. Prior to joining ViroPharma, Mr. Milano was with KPMG LLP, independent certified public accountants, where he was a Senior Manager. Mr. Milano has served on the board of directors of Vanda Pharmaceuticals Inc. since April 2010 and served on the board of directors of Verticalnet, Inc. from August 2003 until the company was acquired by BravoSolution S.p.A. in January 2008. Mr. Milano received his Bachelor of Science degree in Accounting from Rider College.

Charles A. Rowland, Jr. has served as our Vice President, Chief Financial Officer since he joined the company in October 2008. Prior to joining ViroPharma, Mr. Rowland served as Executive Vice President, Chief Financial Officer of Endo Pharmaceuticals from December 2006 to September 2008. Prior thereto, Mr. Rowland was Senior Vice President and CFO of Biovail Pharmaceuticals, Inc. from 2004 to 2006. From 2001 to 2004, he was Chief Operating and Financial Officer for Breakaway Technologies, a management consulting company. His pharmaceutical industry career includes positions of increasing scope and responsibility at Pharmacia Corp., where he had global responsibility for Finance and Information Technology for the Pharmaceutical Business and financial responsibility for the Global Supply organization as Vice President, Finance Global Supply and VP Finance & IT-Global Pharma Ops; Novartis Pharmaceuticals Corp., where he was Vice President, Planning and Decision Support, and Bristol-Myers Squibb, where he served as Director of Finance. Mr. Rowland received his Bachelor of Science degree in Accounting from St. Joseph's University and a MBA from Rutgers University.

Colin Broom, M.D. has served as Vice President, Chief Scientific Officer of ViroPharma since May 2004. From 2000 until 2003, Dr. Broom served as Vice President of Clinical Development and Medical Affairs, Europe, for Amgen. From 1998 to 1999, Dr. Broom served as Senior Vice President of Global Clinical Development for Hoechst Marion Roussel, now Sanofi-Aventis. From 1984 until 1998, Dr. Broom was with Glaxo and then SmithKline Beecham, where he held positions of increasing seniority in clinical pharmacology in Europe before moving to the U.S. to head global oncology and subsequently becoming Vice President of CNS/GI. Dr. Broom holds a Bachelor of Science degree in Pharmacology from University College London, and a Bachelor of Medicine and Bachelor of Surgery degree from St. George's Hospital Medical School. Dr. Broom is a Member of the Royal College of Physicians and a Fellow of the Faculty of Pharmaceutical Medicine of the UK Colleges of Physicians. Dr. Broom has been a director of NPS Pharmaceuticals since July 2009.

Thomas F. Doyle is Vice President, Strategic Initiatives as of January 2008. Mr. Doyle previously served as Vice President, General Counsel of ViroPharma from November 1997 to January 2008, as Secretary from February 1997 to January 2008 and as Executive Director, Counsel since joining ViroPharma in November 1996 to February 1997. From 1990 until 1996, Mr. Doyle was a corporate attorney with the law firm of Pepper Hamilton

LLP. Mr. Doyle received his J.D. from Temple University School of Law. Prior to attending Temple University, Mr. Doyle was a Certified Public Accountant. Mr. Doyle received his Bachelor of Science degree in Accounting from Mt. St. Mary's College.

Daniel B. Soland joined ViroPharma in November 2006 as our Vice President, Chief Commercial Officer and has served as our Chief Operating Officer since March 2008. From February 2005 until June 2006, Mr. Soland served as President of Chiron Vaccines. From March 2003 until February 2005, Mr. Soland was President and Chief Executive Officer at Epigenesis Pharmaceuticals, a privately held biopharmaceutical company. Prior to that, Mr. Soland spent nine years with GlaxoSmithKline as the Vice President and Director of Worldwide Marketing Operations, and five years as GSK's Vice President and Director of the U.S. Vaccines Business Unit. Mr. Soland holds a Bachelor of Science degree in Pharmacy from the University of Iowa, in Iowa City, IA.

Robert G. Pietrusko, Phrm.D., has served as Vice President, Global Regulatory Affairs and Quality since joining ViroPharma in 2007. Prior to joining ViroPharma, Dr. Pietrusko served as Senior Vice President of Worldwide Regulatory Affairs for Millennium Pharmaceuticals, Inc. from 2001 through May 2007. Dr. Pietrusko spent 19 years at GlaxoSmithKline, culminating in his tenure as Vice President and Director, Anti-infective and Antiviral Therapeutic Areas, U.S. Regulatory Affairs. Dr. Pietrusko holds a Bachelor of Science degree in Biology and a Bachelors of Pharmacy degree from Rutgers University, and a Doctor of Pharmacy degree from the Philadelphia College of Pharmacy and Science.

J. Peter Wolf has served as Vice President, General Counsel, and Secretary since January 2008. Mr. Wolf previously served as Associate General Counsel of ViroPharma since 2004. From 1995 to 2004 Mr. Wolf was a corporate attorney at private law firms. Mr. Wolf received his J.D. from the George Washington University National Law Center and his Bachelor of Arts from the University of Delaware.

Robert C. Fletcher has served as Vice President, Business Development and Project Management since January 2005. Mr. Fletcher joined ViroPharma in 2001 as a project leader, and has since held roles of increasing responsibility during his tenure in the areas of business development and project management. Prior to joining ViroPharma, Mr. Fletcher held multiple roles of escalating responsibility at SmithKline Beecham Pharmaceuticals/GlaxoSmithKline, Becton-Dickinson and Company, Zynaxis Inc./Intracell Corporation, and Centocor Corporation. He holds both a master of science degree and a bachelor of arts degree in biology from Wake Forest University.

Richard S. Morris, CPA has served as Vice President, Chief Accounting Officer of ViroPharma since January 2011. From April 2008 until January of 2011, Mr. Morris served as Controller and Chief Accounting Officer. From December 2001 until April 2008, Mr. Morris has served in increasing levels of responsibility at ViroPharma, most recently as Controller from January of 2005 through April 2008. Prior to joining ViroPharma, Mr. Morris worked for KPMG LLP in their Healthcare Assurance practice. Mr. Morris holds a bachelor's degree in Accounting from Saint Joseph's University and has been a CPA since 1999.

Available Information

Our Internet website is www.viropharma.com and you may find our SEC filings on the "Investors" tab of that website. We provide access to all of our filings with the SEC, free of charge, as soon as reasonably practicable after filing with the SEC on such site. Our Internet website and the information contained on that website, or accessible from our website, is not intended to be incorporated into this Annual Report on Form 10-K or any other filings we make with the SEC.

PART II – OTHER INFORMATION

ITEM 1A. Risk Factors

Vancocin sales represent a significant portion of our revenue and a decrease in sales could have a material adverse effect on our business, financial condition, results of operations and liquidity.

If revenue from Vancocin materially declines, our financial condition and results of operations will be materially harmed because sales of Vancocin represented approximately 53 percent of our revenue in 2011. In addition, to the extent that revenue from Vancocin materially declines prior to Cinryze, Buccolam, and Plenadren achieving significant commercial success in Europe, our financial condition and results of operations may be further harmed because sales of Cinryze in the U.S. may be our only other material source of revenue for the next two years.

Vancocin product sales could be adversely affected by a number of factors, including:

- the development and approval of competitive generic versions of oral Vancocin, approval of products which are currently marketed for other indications by other companies or new pharmaceuticals and technological advances to treat the conditions addressed by Vancocin;
- manufacturing or supply interruptions which could impair our ability to acquire an adequate supply of Vancocin to meet demand for the product;
- changes in the prescribing or procedural practices of physicians in the areas of infectious disease, gastroenterology and internal medicine, including prescribing of other competitive products;
- decreases in the rate of infections for which Vancocin is prescribed;
- the level and effectiveness of our sales and marketing efforts;
- decrease in the sensitivity of the relevant bacterium to Vancocin;
- changes in terms required by wholesalers, including “fee-for-service” contracts;
- marketing or pricing actions by one or more of our competitors;
- our ability to maintain all necessary contracts or obtain all necessary rights under applicable federal and state rules and regulations;
- the approval of legislative proposals that would authorize re-importation of Vancocin into the United States from other countries;
- regulatory action by the FDA and other government regulatory agencies;
- changes in the reimbursement or substitution policies of third-party payors or retail pharmacies; and
- product liability claims.

Revenues from the sale of Vancocin may not remain at or above current levels or achieve the level of net product sales that we expect. We believe the rate of infections for which Vancocin is prescribed decreased during the second half of 2007 and remained flat or declined during the period of 2008 to 2011. A decrease in sales of Vancocin could have a material adverse effect on our business, financial condition, results of operations and liquidity.

If we are unable to continue to successfully commercialize Cinryze in the United States, or are delayed in our efforts to commercialize Cinryze in Europe and additional territories, our business will be materially harmed.

The FDA approved Cinryze for routine prophylaxis against angioedema attacks in adolescent and adult patients with hereditary angioedema on October 10, 2008. In June 2011, the European Commission granted us Centralized Marketing Authorization for Cinryze® in adults and adolescents with HAE for routine prevention,

pre-procedure prevention and acute treatment of angioedema attacks. The commercial success of Cinryze will depend on several factors, including the following:

- the number of patients with HAE that may be treated with Cinryze;
- manufacturing or supply interruptions which could impair our ability to acquire an adequate supply of Cinryze to meet demand for the product;
- continued acceptance by physicians and patients of Cinryze as a safe and effective treatment;
- our ability to effectively market and distribute Cinryze in the United States, Europe and additional territories;
- cost effectiveness of HAE treatment using Cinryze;
- relative convenience and ease of administration of Cinryze;
- potential advantages of Cinryze over alternative treatments;
- acceptance and utilization of competitive products;
- patients' ability to obtain sufficient coverage or reimbursement by third-party payors in the United States and our ability to receive sufficient reimbursement and price approvals that are separately required in each country in Europe;
- sufficient supply and reasonable pricing of raw materials necessary to manufacture Cinryze;; and,
- our ability to receive regulatory approvals to market Cinryze in territories outside the United States and Europe in the timeframes we anticipate;

Sales of Cinryze represented approximately 46 percent of our revenue in 2011. If we are not able to continue to successfully commercialize Cinryze in the United States, Europe and additional territories, or are significantly delayed or limited in doing so, we our business, financial condition, results of operations and liquidity could be materially impacted.

If our efforts to commercialize Buccolam in Europe are delayed or are not as successful as we anticipate, our business will be materially harmed.

In September of 2011, the European Commission granted a Centralized Pediatric Use Marketing Authorization (PUMA) for Buccolam, for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from 3 months to less than 18 years of age. The commercial success of BUCCOLAM will depend on several factors, including the following:

- the number of pediatric patients with epilepsy or other prolonged, acute, convulsive seizures that may be treated with BUCCOLAM;
- acceptance by physicians and patients of BUCCOLAM as a safe and effective treatment;
- our ability to effectively market and distribute BUCCOLAM in Europe;
- cost effectiveness of treatment of epilepsy or other prolonged, acute, convulsive seizures using BUCCOLAM;
- relative convenience and ease of administration of BUCCOLAM;
- potential advantages of BUCCOLAM over alternative treatments;
- the timing of the approval of competitive products for the treatment of epilepsy in pediatric patients;
- The timing and levels of pricing approvals that are separately required in each country in Europe; and
- manufacturing or supply interruptions, including delays in the scale-up of the manufacturing process, which could impair our ability to acquire an adequate supply of BUCCOLAM to meet demand for the product including, without limitation, sufficient supply and reasonable pricing of raw materials necessary to manufacture BUCCOLAM.

If we are not able to continue to successfully commercialize BUCCOLAM in Europe, or are significantly delayed or limited in doing so, we could fail to achieve our estimates for peak year sales for BUCCOLAM and our financial condition, results of operations and liquidity could be materially adversely impacted.

Because the target patient population for Cinryze is small and has not been definitively determined, we must be able to successfully identify HAE patients and maintain a significant market share in order to increase revenue and maintain profitability.

The prevalence of HAE patients has not been definitively determined but has been estimated, through market research we have conducted, at up to 11,000 total patients in the United States while the Hereditary Angioedema Association estimates there are 6,500 patients in the United States. Additionally, we believe that HAE affects between 1 in 10,000 and 1 in 50,000 individuals in Europe and other territories worldwide. There can be no guarantee that any of our programs will be effective at identifying HAE patients and the number of HAE patients in the United States or other territories may turn out to be lower than expected or such patients may not be amenable to treatment with Cinryze as not all HAE patients are appropriately treated through routine prophylaxis. Accordingly, our product sales of Cinryze and overall business could be adversely affected if we are unable to identify additional HAE patients to increase revenue and maintain profitability.

Our core patent protection for Vancocin has expired, and the FDA may not agree with our belief that Vancocin meets the requirements for three years of exclusivity, which could result in significant competition from generic products and lead to a significant reduction in sales of Vancocin.

The last core patent protecting Vancocin expired in 1996. As a result, there is a potential for significant competition from generic products that treat the same conditions addressed by Vancocin. Such competition could result in a significant reduction in sales of Vancocin. We believe that regulatory hurdles (notwithstanding the recent actions taken by the FDA's Office of Generic Drugs, Center for Drug Evaluation and Research (OGD), which are described in more detail below and which we are vigorously opposing), as well as product manufacturing trade secrets, know-how and related non-patent intellectual property, may present barriers to market entry of generic competition. However, these barriers may not actually delay or prevent generic competition.

On December 14, 2011, we announced the modernization of labeling for Vancocin Capsules made effective through the FDA's approval of a supplemental new drug application (sNDA). As a result of the sNDA approval, we believe Vancocin meets the requirements for three years of exclusivity, and that generic vancomycin capsules will not be approved during this period. Under FDA's regulations, labeling changes based on new clinical investigations that are essential to approval of the sNDA and to which the applicant has exclusive rights may be entitled to three years of exclusivity, and generic drug labeling cannot include information protected by such three-year exclusivity. The FDA may not agree with our position and may determine not to grant exclusivity through listing an exclusivity code for Vancocin in the Approved Drug Products with Therapeutic Equivalence Evaluations (The Orange Book)

Additionally, a generic may seek approval by omitting labeling protected by three-year exclusivity; however, if such omissions render the generic drug less safe or effective, it cannot be approved until the three-year exclusivity expires. We believe that attempting to omit Vancocin labeling changes protected by exclusivity would render generic versions of Vancocin less safe and effective. However, FDA may conclude that the portion of Vancocin's updated label protected by exclusivity may nonetheless be omitted from the labels of generic products. Ultimately, the decision on a grant of three-year exclusivity and its effect on generic vancomycin capsule approvals resides with the FDA.

The effectiveness of these non-patent-related barriers to competition will depend primarily upon the current or future regulatory approval requirements for any generic applicant, the complexities of the manufacturing process for a competitive product, and our ability to protect Vancocin know-how as a trade secret.

If Vancocin is not granted three years of exclusivity as a result of FDA approval of the sNDA, generic competitors may take advantage of the absence of patent protection for Vancocin to attempt to develop a competing product. We have become aware of information suggesting that other potential competitors are attempting to develop a competing generic product. For example, multiple generic manufacturers have publicly stated that they have filed to receive product approval and commence a marketing launch of a generic version of oral Vancocin. We are not able to predict the time period in which a generic drug may enter the market, as this timing will be affected by a number of factors, including:

- whether an in-vitro method of demonstrating bioequivalence for a locally acting GI drug that has neither been correlated with, nor demonstrated to be predictive of, human *in vivo* bioavailability data is available to an applicant to gain marketing approval by the FDA in lieu of performing clinical studies;
- the nature of any clinical trials which are required, if any;
- the timing of filing an Abbreviated New Drug Application, or an ANDA, the amount of time required by the FDA to review the ANDA and whether a generic drug application is afforded an accelerated review by the FDA;
- the specific formulation of drug for which approval is being sought; and
- the time required to develop appropriate manufacturing procedures.

On March 17, 2006, we learned that the OGD changed its approach regarding the conditions that must be met in order for a generic drug applicant to request a waiver of in-vivo bioequivalence testing for vancomycin hydrochloride capsules. Specifically, we were informed that a generic applicant may be able to request such a waiver provided that dissolution testing demonstrates that the test product is rapidly dissolving at certain specified conditions. This deviated from our understanding of OGD's historical practices which would require, for a poorly-absorbed, locally acting gastrointestinal drug (such as Vancocin) a demonstration of bioequivalence through clinical studies or a demonstration of bioequivalence using an appropriately validated in-vitro methodology.

On March 17, 2006, we filed a Petition for Stay of Action with the FDA regarding the requirements for waivers of in-vivo bioequivalence testing for Vancocin, and we have amended that petition several times through additional filings in support of our opposition to any approach that does not require rigorous scientific methods to demonstrate a rate and extent of drug release to the site of action consistent with good medicine and science.

In December 2008, the FDA changed OGD's 2006 bioequivalence recommendation by issuing draft guidance for establishing bioequivalence to Vancocin which would permit generic products that have the same inactive ingredients in the same quantities as Vancocin, or are Q1 and Q2 the same as Vancocin, and that meet certain other conditions, to demonstrate bioequivalence through comparative dissolution testing. Under this latest proposed method, any generic product that is not Q1 and Q2 the same as Vancocin would need to conduct an in vivo study with clinical endpoints to demonstrate bioequivalence with Vancocin.

The FDA convened a meeting of its Advisory Committee for Pharmaceutical Science and Clinical Pharmacology to discuss bioequivalence recommendations for oral vancomycin hydrochloride capsule drug products on August 4, 2009. The Advisory Committee was asked if the proposed guidelines are sufficient for establishing bioequivalence for generic vancomycin oral capsules. The Advisory Committee voted unanimously in favor of the component of the proposed OGD recommendation that requires bioequivalence to be demonstrated through comparable dissolution in media of pH 1.2, 4.5 and 6.8 for potential vancomycin HCl capsule generic products that (a) contain the same active and inactive ingredients in the same amounts as Vancocin HCl capsules; (b) meet currently accepted standards for assay, potency, purity, and stability (equivalent to those in place for Vancocin HCl capsules); and (c) are manufactured according to cGMP.

The effectiveness of the non-patent-related barriers to competition will depend primarily upon whether or not FDA confirms the exclusivity we believe Vancocin qualifies for in connection with our recently approved

sNDA, whether or not FDA determines that protected labeling can be omitted from the labels of generic products, the current or future regulatory approval requirements for any generic applicant, the complexities of the manufacturing process for a competitive product, and our ability to protect Vancocin know-how as a trade secret.

If FDA's proposed bioequivalence method for Vancocin becomes effective, and either FDA does not agree that our labeling changes made effective through our sNDA warrant exclusivity, or FDA acknowledges such exclusivity but nonetheless determines that generic products would be no less safe or effective in the absence of such labeling changes, then the time period in which a generic competitor could be approved would be reduced and multiple generics may enter the market. The approval of generic copies of Vancocin would materially impact our operating results, cash flows and possibly intangible asset valuations. This could also result in a reduction to the useful life of the Vancocin-related intangible assets. Management currently believes there are no indicators that would require a change in useful life as management believes that Vancocin will continue to be utilized along with generics that may enter the market, and the number of generics and the timing of their market entry is unknown.

We do not have patent protection for the composition of Cinryze or Buccolam and we rely on regulatory exclusivity.

The Orphan Drug Act was created to encourage companies to develop therapies for rare diseases by providing incentives for drug development and commercialization. One of the incentives provided by the act is seven years of market exclusivity for the first product in a class licensed for the treatment of a rare disease. HAE is considered to be a rare disease under the Orphan Drug Act, and companies may obtain orphan drug status for therapies that are developed for this indication. The FDA granted Cinryze seven years of marketing exclusivity to Cinryze C1 inhibitor (human) for routine prophylaxis of HAE pursuant to the Orphan Drug Act. The FDA has granted marketing approval of CSL Behring's product, Berinert® C1-Esterase Inhibitor, Human, for the treatment of acute abdominal or facial attacks of hereditary angioedema and Berinert has received exclusivity pursuant to the Orphan Drug Act. In addition, in the first quarter of 2011, we withdrew our orphan designation in Europe and no longer maintain regulatory exclusivity for Cinryze in Europe. In addition, the EMA and Switzerland have enacted orphan drug legislation and we have received an orphan drug designation under this legislation for Plenadren in the EU, Switzerland and the U.S.

While the marketing exclusivity of an orphan drug would prevent other sponsors from obtaining approval of the same drug compound for the same indication unless the subsequent sponsors could demonstrate clinical superiority or a market shortage occurs, it would not prevent other sponsors from obtaining approval of the same compound for other indications or the use of other types of drugs for the same use as the orphan drug. In the event we are unable to fill demand for Cinryze, it is possible that the FDA may view such unmet demand as a market shortage which could impact the market exclusivity provided by the Orphan Drug Act. Additionally, the United States Congress has considered, and may consider in the future, legislation that would restrict the duration or scope of the market exclusivity of an orphan drug and, thus, we cannot be sure that the benefits to us of the existing statute will remain in effect. We cannot predict when generic competition for Cinryze may arise, if at all, in Europe. We have received a pediatric-use marketing authorization (PUMA) for Buccolam in Europe. The PUMA is a new type of marketing authorization which may be requested for a medicine which is already authorized, but no longer covered by intellectual property rights, and which will be exclusively developed for use in children. A PUMA provides 10 years of market protection as a reward for the development in children. As the PUMA for Buccolam was the first such approval to be granted, the EMA and EC may interpret the legislation in ways which restrict the duration or scope of the market exclusivity of a PUMA and, thus, we cannot be sure that the benefits to us of the existing statute will remain in effect.

We do not know whether Vancocin and Cinryze will continue to be competitive in the markets which they serve.

We currently generate revenues from sales of Vancocin in the United States for the treatment of *C. difficile*-associated diarrhea, or CDAD. Vancocin is also used for the treatment of enterocolitis caused by *Staphylococcus*

aureus (including methicillin-resistant strains). . Vancocin sales for the treatment of CDAD decreased in 2009 from the sales achieved in 2008. Vancocin's share of the United States market for this indication may decrease further due to competitive forces and market dynamics, including an increase in the oral use of intravenous vancomycin or a competing product marketed by Optimer Pharmaceuticals. Metronidazole, a generic product, is regularly prescribed to treat CDAD at costs which are substantially lower than for Vancocin. In addition, products which are currently marketed for other indications by other companies may also be prescribed to treat this indication. Other drugs that are in development by our competitors, including Salix Pharmaceuticals could be found to have competitive advantages over Vancocin.

The FDA approved Cinryze for routine prophylaxis against angioedema attacks in adolescent and adult patients with hereditary angioedema on October 10, 2008 and Cinryze became commercially available for prophylaxis against HAE in December 2009. While we are not aware of other companies which are developing a product for the prophylaxis of HAE in the United States, CSL Behring, Shire and Dyax had products approved for the treatment of acute attacks of HAE during 2009, 2010, 2011 and 2012 and steroid based products are currently used for prophylaxis of HAE. In addition, Pharming NV is currently developing products for the acute treatment of HAE. Approval of new products, or the expanded use of currently available products, to prophylax or treat HAE, could materially and adversely affect our United States sales of Cinryze. In addition, there are currently several products approved for the acute treatment of HAE in Europe. Even if we are successful in receiving regulatory approval for Cinryze in Europe, there can be no assurance that we will be able to achieve market share in accordance with our expectations.

We depend on single manufacturers for certain components used in Buccolam, Vancocin and Cinryze and the loss of any of these suppliers or any supplier in general would have a negative impact on our operations.

We rely on a single supplier of vancomycin, the active pharmaceutical ingredient (API) of Vancocin, and also rely on a single manufacturer of Vancocin capsules. Our third party API supplier and finished product supplier are the only manufacturers qualified by the FDA to manufacture API and Vancocin capsule finished product for distribution and sale in the United States. We are therefore dependent upon these suppliers and attempt to maintain Vancocin inventory levels to meet our current projections, plus a reasonable stock in excess of those projections.

We rely on a single manufacturer of Cinryze. Pursuant to our distribution agreement, Sanquin Blood Supply Foundation will supply us with certain annual minimum and maximum amounts of CINRYZE. In the event that certain events occur which result in Sanquin permanently ceasing to manufacture Cinryze, Sanquin will grant us a perpetual license under its intellectual property related to the Product and assign to us each of the agreements with such third party manufacturers. In consideration thereof, we will pay a one-time fee to Sanquin as well as a royalty on future sales of products. In the event demand for Cinryze is greater than the amount supplied by Sanquin, we will not be able to meet such demand as there are no other sources of supply of Cinryze available to us. In the event Sanquin permanently ceases to manufacture Cinryze, we will need to find an alternate manufacturer of Cinryze. Currently, to our knowledge, there is only one other commercial supplier of C1 esterase inhibitor and that supplier has recently received marketing approval for their product in the United States. Accordingly, in the event Sanquin permanently ceases to manufacture Cinryze, we cannot be certain that we would be able to locate another willing supplier for our product on the terms we require.

There are numerous factors that could cause interruptions in the supply of our products, including regulatory reviews; changes in our sources for manufacturing; or disputes with a manufacturer. Our failure to timely locate and obtain replacement manufacturers as needed and conditions affecting the cost and availability of raw materials are magnified when the suppliers are limited in number. Any interruption in the supply of finished products could hinder our ability to timely distribute our products and satisfy customer demand. If we are unable to obtain adequate product supplies to satisfy our customers' orders, we may lose those orders, our customers may cancel other orders, and they may choose instead to stock and purchase competing products. Supply

interruptions may occur, and our inventory may not always be adequate. This in turn could cause a loss of our market share and negatively affect our revenues. We maintain limited property insurance which would only protect us from physical damage to our assets caused by certain types of occurrences to the extent of the value of the property damaged and would not cover lost revenue.

We currently depend, and will in the future continue to depend, on third parties to manufacture raw, intermediate and finished goods for Vancocin, Cinryze, Buccolam and our product candidates. If these manufacturers fail to meet our requirements and the requirements of regulatory authorities, our future revenues may be materially adversely affected.

We do not have the internal capability to manufacture quantities of pharmaceutical products to supply our clinical or commercial needs under the current Good Manufacturing Practice regulations, or cGMPs, required by the FDA and other regulatory agencies. In order to continue to develop products, apply for regulatory approvals and commercialize our products, we will need to contract with third parties that have, or otherwise develop, the necessary manufacturing capabilities.

There are a limited number of manufacturers that operate under cGMPs that are capable of manufacturing our products and product candidates. As such, if we are unable to enter into supply and processing contracts with any of these manufacturers or processors for our development stage product candidates, there may be additional costs and delays in the development and commercialization of these product candidates. For example, Cinryze is a biologic which requires processing steps that are more difficult than those required for most chemical pharmaceuticals and therefore the third party contracts must have additional technical skills and multiple steps to attempt to control the manufacturing processes.

Problems with these manufacturing processes such as equipment malfunctions, facility contamination, labor problems, raw material shortages or contamination, natural disasters, power outages, terrorist activities, or disruptions in the operations of our suppliers and even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims and insufficient inventory.

If we are required to find an additional or alternative source of supply, there may be additional costs and delays in the development or commercialization of our product candidates. Additionally, the FDA, the EMA and other regulatory agencies routinely inspect manufacturing facilities before approving a new drug application, or NDA, or biologic application, or BLA, for a drug or biologic manufactured at those sites. If any of our manufacturers or processors fails to satisfy regulatory requirements, the approval and eventual commercialization of our products and product candidates may be delayed. For example, in addition to FDA, Sanquin is also subject to the requirements of the European health authorities which may impose on Sanquin obligations relating to facility maintenance and/or equipment modifications that could cause delays in Cinryze production.

In addition, regulatory agencies subject a marketed therapy, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. The discovery of previously unknown problems with a therapy or the facility or process used to produce the therapy could prompt a regulatory authority to impose restrictions on us or delay approvals for new products or could cause us to voluntarily adopt restrictions, including withdrawal of one or more of our products or services from the market.

In connection with several inspections of two facilities maintained by Sanquin, our contract manufacturer for Cinryze, FDA issued notices of observations on FDA Form 483 for each site. The FDA has also issued two complete response letters regarding Cinryze® (C1 Esterase Inhibitor [Human]) industrial scale manufacturing expansion activities. In the February 2012 letter, the FDA issued comments related to a portion of the cleaning validation for industrial scale manufacturing. The FDA also noted that it has not yet completed the review of our January 2012 updated responses to observations on Form 483 specific to the September 2011 inspection of the Amsterdam facility. Responses to the observations on 483 have been provided to the FDA, however, several of

the responses remain the subject of continuing corrective and preventive action procedures. If any of our manufacturers or processors fails to satisfy regulatory requirements, operations at such facility may be halted which could result in our inability to supply product to patients and reduce our revenues.

All of our contract manufacturers must comply with the applicable cGMPs, which include quality control and quality assurance requirements as well as the corresponding maintenance of records and documentation. If our contract manufacturers do not comply with the applicable cGMPs and other FDA regulatory requirements, we may be subject to product liability claims, the availability of marketed products for sale could be reduced, our product commercialization could be delayed or subject to restrictions, we may be unable to meet demand for our products and may lose potential revenue and we could suffer delays in the progress of clinical trials for products under development. We do not have control over our third-party manufacturers' compliance with these regulations and standards. Moreover, while we may choose to manufacture products in the future, we have no experience in the manufacture of pharmaceutical products for clinical trials or commercial purposes. If we decide to manufacture products, we would be subject to the regulatory requirements described above. In addition, we would require substantial additional capital and would be subject to delays or difficulties encountered in manufacturing pharmaceutical products. No matter who manufactures the product, we will be subject to continuing obligations regarding the submission of safety reports and other post-market information.

We are taking steps to increase manufacturing capacity for Cinryze, and a failure to increase timely such capacity could limit the rate at which additional new patients will receive Cinryze and will limit the number of doses provided to patients. This would result in a reduction of potential future revenues.

Pursuant to our distribution agreement, Sanquin Blood Supply Foundation supplies us with certain annual minimum and maximum amounts of C1 INH. We and Sanquin are undertaking process improvements and facility expansions to increase the capacity of the facilities involved in manufacturing Cinryze. Our efforts to increase manufacturing capacity have included several approaches. First, using the current processing scale equipment, an additional chromatography unit (PCP, or parallel chromatography process) was added which enabled the addition of production shifts to increase manufacturing output.

We also are working on industrial scale manufacturing expansion activities. Sanquin must obtain the requisite regulatory approvals for this expansion in order to manufacture Cinryze for us at an increased capacity. In October 2010, the FDA issued a complete response letter regarding the facility to be utilized for the Cinryze industrial scale manufacturing expansion activities. The FDA requested additional information related to both (i) observations at the close of the pre-approval inspection and (ii) review of the technical processes. In February 2012, the FDA issued a second complete response letter which included three comments related to a portion of the cleaning validation for industrial scale manufacturing. We believe that only one of the comments requires additional unplanned activity which can be completed in a relatively short time frame. The FDA also noted that it has not yet completed the review of our January 2012 updated responses to observations on Form 483 specific to the September 2011 inspection of the Amsterdam facility. In order to manufacture Cinryze at the industrial scale we must respond to all FDA questions and satisfactorily complete the FDA review, including providing responses to all open observations on Form 483. While we believe that we will be able to satisfy the comments provided by the FDA in the February 2012 complete response letter in a relatively short time period, we cannot guarantee that the FDA will agree with us in the timeframes we anticipate or at all as biologics such as Cinryze require processing steps that are more complex than those required for most chemical pharmaceuticals. When the industrial scale processing line is fully staffed and registered with FDA, it will provide additional output. This work is still ongoing and there can be no assurance that the personnel and regulatory review issues associated with this effort can be accomplished in a timely manner.

The FDA may view the data regarding our cleaning validation or our responses to observations on Form 483 as insufficient or inconclusive, request additional data, require additional conformance batches, delay any decision past the time frames anticipated by us, or deny the approval of the industrial scale manufacturing process. In addition, delays could arise as a result of many factors, including but not limited to, the availability of necessary equipment, validation of such equipment, the timing of regulatory reviews and approvals.

The number of patients enrolling into our treatment support service for patients with HAE and their healthcare providers, *CinryzeSolutions*, has periodically exceeded our expectations. For example, in 2010 we temporarily limited the rate at which additional patients were started on drug to ensure that those already receiving commercial product continue with a supply of Cinryze until capacity increases. During the fourth quarter of 2011, we reduced the amount of Cinryze inventory held by our distributors and by patients. If our manufacturing capacity expansion projects at Sanquin are delayed, or do not result in the capacity we anticipate, or if Sanquin cannot obtain necessary regulatory approvals for the contemplated facility expansions in the time frames we anticipate, , we may not be able to satisfy patient demand. Additionally, in the event Sanquin is not able to manufacture the anticipated volume of product at the existing scale, as a result of either batch failures, variability in batch yields, required maintenance or other causes, we may not be able to satisfy patient demand. Our inability to obtain adequate product supplies to satisfy our patient demand may create opportunities for our competitors and we will suffer a loss of potential future revenues.

The distribution of our commercial products in the U.S. is dependent upon a limited number of third party service providers and disruptions in these relationships could result in our failure to achieve the sales of our products that we expected.

We rely on a single third party to provide all necessary distribution and logistics services with respect to our sales of Vancocin and Cinryze, including warehousing of finished product, accounts receivable management, billing, collection and recordkeeping. The third party logistics service provider stores and distributes Vancocin from two warehouses located in the central United States and western United States and Cinryze from one of these warehouses. A disaster occurring at or near these facilities could materially and adversely impact our ability to supply Vancocin and Cinryze to our distribution partners, which would result in a reduction in revenues from sales.

Approximately 95 percent of our Vancocin sales are to the three largest pharmaceutical wholesalers. If any of these wholesalers ceases to purchase our product for any reason, then unless and until the remaining wholesalers increase their purchases of Vancocin or alternative distribution channels are established:

- our commercial operations could be significantly disrupted;
- the availability of our products to patients could be disrupted; and
- we may not achieve the sales of our products that we expected, which could decrease our revenues and potentially affect our ability to maintain profitability.

Additionally, we do not require collateral from our wholesalers but rather maintain credit limits and as a result we have an exposure to credit risk in our accounts receivable. The highest account receivable during 2011 we experienced from any one wholesaler was approximately \$25.0 million and we anticipate that this amount could increase if Vancocin sales increase. While we have experienced prompt payment by wholesalers and have not had any defaults on payments owed, a default by a large wholesaler could have a material adverse effect on our results of operations.

We have entered into agreements with two specialty distributors / specialty pharmacies that distribute Cinryze to physicians, hospitals, pharmacies, home health providers and patients.

If our third party service providers cease to be able to provide us with these services, or do not provide these services in a timely or professional manner, it could significantly disrupt our commercial operations, and may result in our not achieving the sales of Vancocin and Cinryze that we expected. Additionally, any interruption to these services could cause a delay in delivering product to our customers, which could have a material adverse effect on our business.

If we are unable to obtain reimbursement for Cinryze from government health administration authorities, private health insurers and other organizations, Cinryze may be too costly for regular use and our ability to generate revenues would be harmed.

Our future revenues and profitability will be adversely affected if governmental, private third-party payors and other third-party payors, including Medicare and Medicaid, do not sufficiently defray the cost of Cinryze to the consumer. If these entities do not provide coverage and reimbursement for Cinryze or determine to provide an insufficient level of coverage and reimbursement, Cinryze may be too costly for general use, and physicians may not prescribe it. Cinryze is significantly more expensive than traditional drug treatments. Many third-party payors cover only selected drugs, making drugs that are not preferred by such payor more expensive for patients, and often require prior authorization or failure on another type of treatment before covering a particular drug. Third-party payors may be especially likely to impose these obstacles to coverage for higher-priced drugs such as Cinryze.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability and worsen our financial condition. In the United States and elsewhere, there have been, and we expect there will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payors are challenging the prices charged for healthcare products and increasingly limiting and attempting to limit both coverage and level of reimbursement for prescription drugs.

Because Cinryze is too expensive for most patients to afford without sufficient health insurance coverage, if adequate coverage and reimbursement by third-party payors is not available, our ability to successfully commercialize Cinryze may be adversely impacted. Any limitation on the use of Cinryze or any decrease in the price of Cinryze will have a material adverse effect on our business.

Even where patients have access to insurance, their insurance co-payment amounts may be too expensive for them to afford. We financially support the HAE financial assistance programs established by Patient Services Incorporated (PSI), which, among other things, assists patients in acquiring drugs such as Cinryze. Organizations such as PSI assist patients who have no insurance coverage for drugs, locate insurance, and also provide financial assistance to patients whose insurance coverage leaves them with prohibitive co-payment amounts or other expensive financial obligations. In addition to assistance from organizations such as PSI, we provide Cinryze without charge for related charitable purposes. We are not able to predict the financial impact of the support we may provide for these and other charitable purposes; however, substantial support could have a material adverse effect on our ability to maintain profitability.

In furtherance of our efforts to facilitate access to Cinryze, we have established the CinryzeSolutions™ program, a treatment support service for patients with HAE and their healthcare providers. CinryzeSolutions personnel provide education about HAE and Cinryze and help facilitate solutions for reimbursement, coverage and access. Although case managers assist patients and healthcare providers in locating and accessing Cinryze, we cannot guarantee a sufficient level of coverage, reimbursement or financial assistance.

In European countries where we sell or are seeking or may seek to commercialize Cinryze, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control. We may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us, or such coverage, pricing, and reimbursement may differ in separate regions in the same country. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country, and we cannot guarantee that we will have the capabilities or resources to successfully conclude the necessary processes and commercialize Cinryze in every or even most countries in which we seek to sell Cinryze. Reimbursement sources are different in each country and in each country may include a combination of distinct potential payers, including private insurance and governmental payers. For example, countries in the European Union may restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for

human use. A member state may from time to time approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Some countries have or may seek to impose limits on the aggregate reimbursement for Cinryze or for the use of Cinryze for certain indications. In such cases, our commercial operations in such countries and our results of operations and our business are and may be adversely affected. Our results of operations may suffer if we are unable to successfully and timely conclude reimbursement, price approval or funding processes and market Cinryze in such foreign countries or if coverage and reimbursement for Cinryze is limited or reduced. If we are not able to obtain coverage, pricing or reimbursement on terms acceptable to us or at all, or if such terms should change in any foreign countries, we may not be able to or we may determine not to sell Cinryze for one or more indications in such countries, or we could decide to sell Cinryze at a lower than anticipated price in such countries, and our revenues may be adversely affected as a result

If supplies of human plasma are interrupted or if we are unable to acquire adequate supplies of human plasma to meet demand for Cinryze, our ability to maintain inventory levels could suffer and future revenues may be delayed or reduced.

We have relied exclusively and are dependent on certain third party sources to supply human plasma for Cinryze. In connection with our commercial sales of Cinryze and our ongoing and future clinical trials, we will need increased supplies of plasma.

We are responsible for obtaining an adequate supply of United States source plasma to meet demand for Cinryze in the United States. Pursuant to our manufacturing and distribution agreement, Sanquin is responsible for providing European plasma for Cinryze sold in the European market. We have a contract for the purchase and sale of plasma with DCI Management Group, LLC, pursuant to which we purchase specified quantities of United States source plasma. Under this agreement, DCI agreed to sell us specified annual quantities of United States source plasma in accordance with applicable good manufacturing practices. In addition to DCI, we entered into a Strategic Supply Agreement with Biotest Pharmaceuticals Corporation (BPC) pursuant to which we will purchase certain quantities of United States source plasma. Our contractual purchase commitments are subject to annual percentage increases based on change in the consumer price index and are subject to other market conditions. BPC has also built three additional plasma centers to support our plasma requirements during the term of the agreement. We have an option to purchase these three plasma centers. We have also made periodic spot purchases of United States source plasma.

Plasma markets have historically been subject to price fluctuations as a result of changes in the production capacity available in the industry, the availability and pricing of plasma, development of competing products and the availability of alternative therapies. In addition, some plasma derived products are currently in clinical development for indications, including Alzheimer's disease, that, if approved, could cause a substantial increase in the demand for, and price of, plasma. In recent years, there has been consolidation in the industry as several plasma derivatives manufacturers have acquired plasma collectors and reduced capacity. As a result, it could be difficult to resolve any significant disruption in the supply of plasma. In addition, concern over the safety of blood products (which has led to increased domestic and foreign regulatory control over the collection and testing of plasma and the disqualification of certain segments of the population from the donor pool), have reduced the potential donor pool. In addition, the EMA requires that all United States human plasma imported into Europe is sourced from plasma collection centers that are approved by a competent European authority, which limits the number of plasma collection centers available for sourcing of United States human plasma and potentially increases the costs.

If we are unable to obtain or maintain the level of plasma supply we require, we will need to obtain our supply from other parties in order to satisfy our expected needs. Establishing additional or replacement suppliers for plasma may take a substantial amount of time. In addition, we may have difficulty obtaining similar supplies from other suppliers that are acceptable to the FDA or EMA. If we have to switch to a replacement supplier, we may face additional regulatory delays and the manufacture and delivery of Cinryze could be interrupted for an extended period of time, which may decrease sales of Cinryze or result in increased costs.

Cinryze is derived from human plasma, and is therefore subject to the risk of biological contamination inherent in plasma-derived products. This risk could adversely affect our ability to obtain raw materials and market our products.

Cinryze is derived from donated human plasma. Many disease-causing viruses, bacteria and other pathogens are present in the plasma of infected individuals. If infected individuals donate plasma, the plasma would likely contain those pathogens. As a result, the sourcing of plasma, and the production of products derived from plasma, is regulated extensively by the FDA and other medical product and health care regulatory agencies. We rely on our suppliers to maintain compliance with the regulations promulgated by such agencies. The failure to comply with these regulations or the accidental contamination of plasma could adversely affect our ability to source plasma at commercially reasonable prices. Moreover, public perception about the safety of plasma-derived products could adversely affect the market for our products. Concern over the safety of plasma-derived products, driven in part by past screening failures in the industry and the appearance of infectious agents like HIV, has resulted in the adoption of rigorous screening procedures by regulatory authorities, and screening procedures are likely to become stricter and more complex over time. As screening procedures have become more rigorous, potential donors have been disqualified and other potential donors have been discouraged from donating due to their reluctance to undergo the required screening procedures. Increasingly stringent measures could adversely affect plasma supplies, with a corresponding adverse effect on our ability to obtain raw materials at a commercially acceptable price, or at all. The safety concerns associated with plasma-derived products also affect our ability to market our products. Medical events or studies that raise or substantiate concerns about the safety of our or other similar products would negatively impact public perception of all plasma-derived products and of the plasma donation process. Further, any failure in screening, whether by us or by other manufacturers of these products, could adversely affect our reputation, the support we receive from the medical community and overall demand for our products.

If patients using our commercial products suffer injuries, even if unrelated to our products, our regulatory approvals could be revoked or otherwise negatively impacted and we may be subject to product liability claims, which can be expensive, difficult to defend and may result in large judgments or settlements against us.

The administration of drugs or biologics to humans, whether in clinical trials or after marketing clearance is obtained, can result in product liability claims. Product liability claims can be expensive, difficult to defend and may result in large judgments or settlements against us. In addition, third party collaborators and licensees may not protect us from product liability claims.

We market two commercial products in the US and will market three products in the EU during 2012. As HAE and treatment of adrenal insufficiency are rare disease, we tested Cinryze and Plenadren in only a small number of patients. As more patients use Cinryze and Plenadren, new risks and side effects may be discovered, the rate of known risks or side effects may increase, and risks previously viewed as less significant could be determined to be significant. Previously unknown risks and adverse effects of our products may also be discovered in connection with unapproved, or off-label, uses of our products. We are conducting required post approval studies in the US and EU with Cinryze and Plenadren. Clinical evaluations of outcomes of these studies as well as in the post-marketing setting are required to be reported to appropriate regulatory agencies in accordance with relevant regulations.

In addition, we are studying and expect to continue to study Cinryze in diseases other than HAE in controlled clinical settings, and independent investigators are doing so as well. In the event of any new risks or adverse effects discovered as new patients are treated for approved indications and as Cinryze is studied in or used by patients for off-label indications, regulatory authorities may delay or revoke their approvals, we may be required to conduct additional clinical trials, make changes in labeling of Cinryze, reformulate Cinryze or make changes and obtain new approvals for our and our suppliers' manufacturing facilities.

The discovery of previously unknown risks and side effects of our products could result in a significant drop in the potential sales of our products, experience harm to our reputation and the reputation of our products in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our products or substantially increase the costs and expenses of commercializing and marketing our products.

We may be sued by people who use our products, whether as a prescribed therapy, during a clinical trial, during an investigator initiated study, or otherwise. Any informed consents or waivers obtained from people who enroll in our trials or use our products and product candidates may not protect us from liability or litigation. In addition, negative publicity relating to the use of our products or a product candidate, or to a product liability claim, may make it more difficult, or impossible, for us to market and sell our products.

We currently maintain product liability insurance in connection with our clinical development programs and marketed products. We may not be able to obtain or maintain adequate protection against potential liabilities arising from clinical development or product sales. If we are unable to obtain sufficient levels of insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to product liability claims. A successful product liability claim in excess of our insurance coverage could harm our financial condition, results of operations, liquidity and prevent or interfere with our product commercialization efforts. In addition, any successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable terms. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

In order to continue to expand our business and sustain our revenue growth, we will need to acquire additional marketed products or product candidates in clinical development through in-licensing or the acquisitions of businesses that we believe are a strategic fit with us. We may not be able to in-license or acquire suitable products at an acceptable price or at all. In addition, engaging in any in-licensing or acquisitions will incur a variety of costs, and we may never realize the anticipated benefits of any such in-license or acquisition.

As part of our long-term strategy and in order to sustain our revenue growth, we intend to seek to acquire or in-license additional marketed products or product candidates in clinical development that treat serious or life threatening illnesses, which treat high unmet medical needs, which require limited commercial infrastructure, and that have the potential to provide both top and bottom line growth. Even if we are able to locate products, product candidates in clinical development or businesses that fit within our strategic focus, we cannot assure you that we will be able to negotiate agreements to acquire or in-license such additional products or product candidates in clinical development on acceptable terms or at all. Further, if we acquire a product, product candidates in clinical development or business, the process of integrating the acquired product, product candidates in clinical development or business may result in unforeseen operating difficulties and expenditures and may divert significant management attention from our ongoing business operations. Moreover, we may fail to realize the anticipated benefits for a variety of reasons, such as an acquired product candidate proving to not be safe or effective in later clinical trials. We may fund any future acquisition by issuing equity or debt securities, which could dilute the ownership percentages of our existing stockholders. Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote resources to potential acquisitions that are never completed. We cannot assure you that an acquired product, product candidates in clinical development or business will have the intended effect of helping us to sustain our revenue growth. If we are unable to do so, our business could be materially adversely affected.

Our long-term success depends upon our ability to develop, receive regulatory approval for and commercialize drug product candidates and, if we are not successful, our ability to generate revenues from the commercialization and sale of products resulting from our product candidates will be limited.

All of our drug candidates will require governmental approvals prior to commercialization. Our failure to develop, receive regulatory approvals for and commercialize our development stage product candidates successfully will prevent us from generating revenues from the sale of products resulting from our product candidates. Our product candidates are in the development stage and may not be shown to be safe or effective.

Cinryze

We are currently evaluating with our partner Sanquin, the feasibility of additional indications and/or other formulations for Cinryze. We plan to initially focus on C-1 mediated diseases affecting transplant patients, including AMR and DGF. We also intend to seek approval to market Cinryze in certain additional territories throughout the world outside of the United States and Europe.

Non-toxigenic difficile

In February 2006, we entered into a licensing agreement for the rights to develop non-toxigenic strains of *C. difficile*, or VP20621, for the treatment and prevention of CDAD. We plan to initially focus our efforts on the opportunity to prevent recurrence of CDAD following treatment with antibiotics such as Vancocin. On May 19, 2011 we announced that dosing had begun in the initiation of a Phase 2 dose-ranging clinical study to evaluate the safety, tolerability, and efficacy of VP 20621 for prevention of recurrence of *Clostridium difficile* infection in adults previously treated for CDAD. We may not be successful in completing the phase 2 study in the time frame we anticipate. Following completion of the phase 2 study, a phase 3 study is planned although the results of the clinical trials may not support further clinical development.

VP-20629, or indole-3-propionic acid

In September 2011, we entered in to a licensing agreement for the worldwide rights to develop VP-20629, or indole-3-propionic acid for the treatment of Friedreich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease. We expect to initiate a phase 2 study within 12 to 18 months after completion of longer term toxicology studies. We may not be successful in completing the phase 2 study in the time frame we anticipate. Following completion of the phase 2 study, a phase 3 study is planned although the results of the clinical trials may not support further clinical development.

We cannot be certain that our efforts and the efforts of our partners regarding our product candidates will lead to commercially viable products. Negative, inconclusive or inconsistent clinical trial results could prevent regulatory approval, increase the cost and timing of regulatory approval, cause us to perform additional studies or to file for a narrower indication than planned. We do not know what the final cost to manufacture product candidates in commercial quantities will be, or the dose required to treat patients and, consequently, what the total cost of goods for a treatment regimen will be.

If we are unable to successfully develop our product candidates, we will not have a source of revenue other than Vancocin, Cinryze, Buccolam and Plenadren. Moreover, the failure of one or more of our product candidates in clinical development could harm our ability to raise additional capital. Furthermore, results from our clinical trials may not meet the level of statistical significance required by the FDA or other regulatory authorities for approval of a drug candidate.

The development of any of our product candidates is subject to many risks, including that:

- the product candidate is found to be ineffective or unsafe;
- the clinical test results for the product candidate delay or prevent regulatory approval;

- the FDA, EMA, or other regulatory authorities forbid us to initiate or continue testing of the product candidates in human clinical trials;
- the product candidate cannot be developed into a commercially viable product;
- the product candidate is difficult and/or costly to manufacture;
- the product candidate later is discovered to cause adverse effects that prevent widespread use, require withdrawal from the market, or serve as the basis for product liability claims;
- third party competitors hold proprietary rights that preclude us from marketing the product candidate; and
- third party competitors market a more clinically effective, safer, or more cost-effective product.

Even if we believe that the clinical data sufficiently demonstrates the safety and efficacy of a product candidate, regulators may disagree with us, which could delay, limit or prevent the approval of such product candidate. In addition, regulatory approval may take longer than we expect as a result of a number of factors, including failure to qualify for priority review of our application. All statutes and regulations governing the approval of our product candidates are subject to change in the future. These changes may increase the time or cost of regulatory approval, limit approval, or prevent it completely.

The foreign regulatory approval process includes all of the risks associated with FDA approval set forth above, as well as additional country-specific regulations. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Even if we receive regulatory approval for our product candidates, or acquire the rights to additional products which have received regulatory approvals, the later discovery of previously unknown problems with a product, manufacturer or facility may result in adverse consequences, including withdrawal of the product from the market. Approval of a product candidate may be subject to a risk evaluation mitigation strategy may be conditioned upon certain limitations and restrictions as to the drug's use, or upon the conduct of further studies, and may be subject to continuous review.

The regulatory process is expensive, time consuming and uncertain and may prevent us from obtaining required approvals for the commercialization of our product candidates.

We have a product candidate, VP20621, for the treatment and prevention of CDAD in clinical development. In addition, we are currently evaluating with our partner Sanquin, the feasibility of additional therapeutic uses and potential indications as well as other modes of administration for Cinryze. We expect to conduct clinical studies during 2012 to assess at least one additional therapeutic use of Cinryze as well as continue to study the sub-cutaneous administration of Cinryze. We may also initiate clinical studies for other product candidates, including VP-20629, or indole-3-propionic acid for the treatment of Friedreich's Ataxia. We must complete significant laboratory, animal and clinical testing on these product candidates before submitting marketing applications in the United States and abroad.

The rate of completion of clinical trials depends upon many factors, including the rates of initiation of clinical sites and enrollment of patients. If we are unable to initiate a sufficient number of clinical sites and accrue sufficient clinical patients who are eligible to participate in the trials during the appropriate period, we may need to delay our clinical trials and incur significant additional costs. In addition, the FDA, Independent Safety Monitoring Boards or Institutional Review Boards may require us to delay, restrict, or discontinue our clinical

trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. In addition, we may be unable to submit a NDA to the FDA or marketing petitions to other regulatory authorities such as the EMEA for our product candidates within the time frame we currently expect, or at all. Once an NDA or other form of petition for marketing authority is submitted, it must be approved by the FDA or other regulatory authority before we can commercialize the product described in the application. The cost of human clinical trials varies dramatically based on a number of factors, including:

- the number, order and timing of clinical indications pursued;
- the number of patients required for enrollment;
- the length of time required to enroll these patients;
- the costs and difficulty of obtaining clinical supplies of the product candidate; and
- the difficulty in obtaining sufficient patient populations and clinicians.

Even if we obtain positive preclinical or clinical trial results in initial studies, future clinical trial results may not be similarly positive. As a result, ongoing and contemplated clinical testing, if permitted by governmental authorities, may not demonstrate that a product candidate is safe and effective in the patient population and for the disease indications for which we believe it will be commercially advantageous to market the product. The failure of our clinical trials to demonstrate the safety and efficacy of our product candidate for the desired indications could delay the commercialization of the product.

In 2003, Congress enacted the Pediatric Research Equity Act requiring the development and submission of pediatric use data for new drug products. In Europe, a Pediatric Investigational Plan must be agreed before a Marketing Authorization Application (MAA) can be submitted. Our failure to obtain these data, or to obtain a deferral of, or exemption from, these requirements could adversely affect our chances of receiving regulatory approval, or could result in regulatory or legal enforcement actions.

Healthcare reform could adversely affect our revenue and financial results.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or PPACA, is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. Several provisions of the new law, which have varying effective dates, may affect us and will likely increase certain of our costs. For example, an increase in the Medicaid rebate rate from 15.1% to 23.1% became effective as of January 1, 2010, and the volume of rebated drugs was expanded to include beneficiaries in Medicaid managed care organizations, effective as of March 23, 2010. The PPACA also imposes an annual fee on pharmaceutical manufacturers which began in 2011, based on the manufacturer's sale of branded pharmaceuticals and biologics (excluding orphan drugs); expands the 340B drug discount program (excluding orphan drugs) including the creation of new penalties for non-compliance; and includes a 50% discount on brand name drugs for Medicare Part D participants in the coverage gap, or "doughnut hole". Substantial new provisions affecting compliance also have been added, which may require us to modify our business practices with health care practitioners. In addition, the new law establishes an abbreviated licensure pathway for products that are biosimilar to FDA-approved biological products, such as Cinryze, with provisions covering exclusivity periods and a specific reimbursement methodology for biosimilars.

The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of the PPACA cannot be known until these provisions are implemented and the Centers for Medicare & Medicaid Services and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products. We will continue to evaluate the PPACA, as amended, the implementation of

regulations or guidance related to various provisions of the PPACA by federal agencies, as well as trends and changes that may be encouraged by the legislation and that may potentially impact on our business over time.

Organizations, states and lawmakers who opposed the passage of PPACA threatened to take legal action against it upon its passage and several court challenges are currently at various stages of development. In addition, there have been several bills introduced in Congress to repeal PPACA. The uncertainty regarding the probability of success of these efforts could cause delays in the implementation of various provisions of PPACA. In the event PPACA is either overturned by a court proceeding or repealed through a legislative process, a disruption in reimbursement of our products may occur.

In addition, Federal, state, and foreign governmental authorities are likely to continue efforts to control the price of drugs and reduce overall healthcare costs. These efforts could impact our ability to market products and generate revenues in the United States and foreign countries.

Our strategic plan may not achieve the intended results.

We made the strategic decision to focus on the development of later stage opportunities by expanding our product portfolio through the acquisition of complementary clinical development stage or commercial product opportunities as a means to accelerate our path toward becoming a profitable pharmaceutical company. As a result of this strategic decision, we substantially discontinued our early stage activities, and do not maintain discovery research or significant internal preclinical development capabilities.

We may not be successful in executing our strategy. We may not be able to in-license or acquire suitable products at an acceptable price, or at all. In addition, engaging in any in-licensing or acquisition will incur a variety of costs, and we may never realize the anticipated benefits of any such in-license or acquisition. We may need additional financing in order to acquire additional new products or product candidates. Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote resources to potential acquisitions that are never completed.

We cannot assure you that an acquired product, product candidates in clinical development or business will have the intended effect of helping us sustain our revenue growth in the near term or longer term. If we are unable to do so, our business could be materially adversely affected.

We depend on collaborations with third parties, which may reduce our product revenues or restrict our ability to commercialize products, and also ties our success to the success of our collaborators.

We have entered into, and may in the future enter into additional, sales and marketing, distribution, manufacturing, development, licensing and other strategic arrangements with third parties.

Sales of Cinryze are dependent on distribution rights that we have received from Sanquin pursuant to a distribution agreement relating to the treatment of HAE in the United States and a separate agreement related to other territories. During the term of the agreement, Sanquin will supply us with our commercial requirements for C1 INH for the treatment of HAE in each country where we have received regulatory approval, subject to minimum annual purchase requirements in Euros equal to approximately €26.6 (approximately \$34.4 million) million per year, net of the agreed upon discount.

In December 2011, we entered into a development and option agreement with Meritage Pharma, Inc. (Meritage) under which we agreed to make certain payments to Meritage to facilitate Meritage's development of the oral budesonide suspension for the treatment of eosinophilic esophagitis in exchange for an irrevocable option to acquire Meritage.

In September 2011, we entered into a license agreement with INS under which we acquired an exclusive worldwide license to develop, manufacture, distribute, market and sell products containing indole-3-propionic acid, or VP-20629. We intend to develop a licensed product containing VP-20629 for the treatment of Friedreich's Ataxia.

In August 2003, we entered into a license agreement with GSK under which we acquired exclusive worldwide rights, excluding Japan, from GSK to develop and commercialize an antiviral compound, maribavir, for the prevention and treatment of CMV infections related to transplant, including solid organ and hematopoietic stem cell bone marrow transplantation, congenital transmission, and in patients with HIV infection. GSK retained the exclusive right to market and sell products covered by these patents and patent applications in Japan.

We are currently engaged in additional discussions relating to other arrangements. We cannot be sure that we will be able to enter into any such arrangements with third parties on terms acceptable to us or at all. Third party arrangements may require us to grant certain rights to third parties, including exclusive marketing rights to one or more products, or may have other terms that are burdensome to us.

Our ultimate success may depend upon the success of our collaborators. We have obtained from Sanquin, INS and GSK, and will attempt to obtain in the future, licensed rights to certain proprietary technologies and compounds from other entities, individuals and research institutions, for which we may be obligated to pay license fees, make milestone payments and pay royalties. Our agreement with Meritage requires us to rely upon their efforts to advance the clinical development of OBS. In addition, we may in the future enter into collaborative arrangements for the marketing, sales and distribution of our product candidates, which may require us to share profits or revenues. We may be unable to enter into additional collaborative licensing or other arrangements that it needs to develop and commercialize its drug candidates. Moreover, we may not realize the contemplated benefits from such collaborative licensing or other arrangements. These arrangements may place responsibility on our collaborative partners for preclinical testing, human clinical trials, the preparation and submission of applications for regulatory approval, or for marketing, sales and distribution support for product commercialization. We cannot be certain that any of these parties will fulfill their obligations in a manner consistent with our best interest. These arrangements may also require us to transfer certain material rights or issue our equity securities to corporate partners, licensees or others. Any license or sublicense of our commercial rights may reduce our product revenue. Moreover, we may not derive any revenues or profits from these arrangements. In addition, our current strategic arrangements may not continue and we may be unable to enter into future collaborations. Collaborators may also pursue alternative technologies or drug candidates, either on their own or in collaboration with others, that are in direct competition with us.

If we fail to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third parties, we could lose license rights that are important to our business.

Our rights to Cinryze is based upon intellectual property that we have licensed from Sanquin and two of our current product candidates are based on intellectual property that we have licensed from INS and GSK. We depend, and will continue to depend, on these license agreements. All of our license agreements may be terminated if, among other events, we fail to satisfy our obligations as they relate to the development of the particular product candidate. All of our license agreements, other than the agreements with Lilly regarding Vancocin, may also be terminated if we breach that license agreement and do not cure the breach within specified time periods or in the event of our bankruptcy or liquidation. Our agreement with Lilly permits us to suspend the licenses granted to us by Lilly in the event of uncured defaults by us until such time as the default is cured or otherwise resolved.

Our agreement with Sanquin includes minimum purchase requirements and our license agreements with INS and GSK impose various obligations on us, including milestone payment requirements and royalties. If we fail to comply with these obligations, Sanquin, INS and GSK may have the right to terminate the license, in which event we would not be able to market products covered by the license.

Disputes may arise with respect to our licensing agreements regarding manufacturing, development and commercialization of any of the particular product candidates. These disputes could lead to delays in or the termination of the development, manufacture and commercialization of our product candidates or to litigation.

Many other entities seek to establish collaborative arrangements for product research and development, or otherwise acquire products, in competition with us.

We face competition from large and small companies within the pharmaceutical and biotechnology industry, as well as public and private research organizations, academic institutions and governmental agencies in acquiring products and establishing collaborative arrangements for product development. Many of the companies and institutions that compete against us have substantially greater capital resources, research and development staffs and facilities than we have. These entities represent significant competition to us as we seek to expand further our pipeline through the in-license or acquisition of additional products in clinical development, or that are currently on the market. Moreover, while it is not feasible to predict the actual cost of acquiring additional product candidates, that cost could be substantial. We may need additional financing in order to acquire additional new products.

There are many potential competitors with respect to our product candidates under development, who may develop products and technologies that make our products and/or technologies non-competitive or obsolete.

There are many entities, both public and private, including well-known, large pharmaceutical companies, chemical companies, biotechnology companies and research institutions, engaged in developing pharmaceuticals for applications similar to those targeted by our products under development.

In May 2011, FDA approved Optimer Pharmaceuticals' product, Dificid® (fidaxomicin), for the treatment of CDAD. We are also aware of several product candidates in clinical development which may compete with VP20621. Merck & Co., Inc. licensed a monoclonal antibody developed by Massachusetts Biological Labs which is in Phase II clinical trials for treatment of CDAD. Additionally, SanofiAventis is developing a *C. difficile* vaccine which is in Phase II studies for the prevention and recurrence of CDAD. Developments by these or other entities may render our product candidates non-competitive or obsolete. Furthermore, many of our competitors have greater resources available to them to assist with development and commercialization, obtaining regulatory approvals and product manufacturing and marketing. Accordingly, our competitors may succeed in obtaining regulatory approval for products more rapidly and more effectively than we do for product candidates. Competitors may succeed in developing products that are more effective and less costly than any that we develop and also may prove to be more successful in the manufacturing and marketing of products.

Any product that we successfully develop and for which we gain regulatory approval must then compete for market acceptance and market share. Accordingly, important competitive factors, in addition to completion of clinical testing and the receipt of regulatory approval, will include product efficacy, safety, timing and scope of regulatory approvals, availability of supply, marketing and sales capacity, reimbursement coverage, pricing and patent protection. Our products could also be rendered obsolete or uneconomical by regulatory or competitive changes.

Any of our future products may not be accepted by the market, which would harm our business and results of operations.

Even if our product candidates are approved by the FDA and other regulatory authorities, they may not achieve market acceptance by patients, prescribers and third-party payors. As a result, we may not receive revenues from these products as anticipated. The degree of market acceptance will depend upon a number of factors, including:

- the receipt and timing of regulatory approvals, and the scope of marketing and promotion activities permitted by such approvals (e.g., the "label" for the product approved by the FDA);
- the availability of third-party reimbursement from payors such as government health programs and private health insurers;
- the establishment and demonstration in the medical community, such as doctors and hospital administrators, of the clinical safety, efficacy and cost-effectiveness of drug candidates, as well as their advantages over existing treatment alternatives, if any;

- the effectiveness of the sales and marketing force that may be promoting our products; and
- the effectiveness of our contract manufacturers.

If our product candidates do not achieve market acceptance by a sufficient number of patients, prescribers and third-party payors, our business will be materially adversely affected.

Funding, especially on terms acceptable to us, may not be available to meet our future capital needs.

Global market and economic conditions have been, and continue to be, disruptive and volatile. The debt and equity capital markets have been impacted by significant write-offs in the financial services sector and the re-pricing of credit risk in the broadly syndicated market, among other things.

If funding is not available when needed, or is available only on unfavorable terms, meeting our capital needs or otherwise taking advantage of business opportunities, such as acquisitions, may become challenging, which could have a material adverse effect on our business plans, revenues and results of operations.

Historically, Vancocin has been subject to limitations on the amount of payment and reimbursement available to patients from third party payors.

Historically, only a portion of the cost of Vancocin prescriptions has been paid for or reimbursed by managed care organizations, government and other third party payors. This reimbursement policy makes Vancocin less attractive, from a net-cost perspective, to patients and, to a lesser degree, prescribing physicians. For example, metronidazole, a drug frequently prescribed for CDAD, is significantly less expensive than Vancocin. If adequate reimbursement levels are not provided for Vancocin, or if reimbursement policies increasingly favor other products, our market share and net sales could be negatively affected, as could our overall business and financial condition.

Our successful commercialization of our product candidates will depend, in part, on the availability and adequacy of third party reimbursement.

Our ability to commercialize our product candidates successfully will depend, in part, on the extent to which reimbursement for the cost of such products and related treatments will be available from government health administration authorities, such as Medicare and Medicaid in the United States, private health insurers and other organizations. Federal and state regulations govern or influence the reimbursement to health care providers of fees in connection with medical treatment of certain patients. In the United States, there have been, and we expect there will continue to be, a number of state and federal proposals that could limit the amount that state or federal governments will pay to reimburse the cost of drugs. Continued significant changes in the health care system could have a material adverse effect on our business. Decisions by state regulatory agencies, including state pharmacy boards, and/or retail pharmacies may require substitution of generic for branded products, may prefer competitors' products over our own, and may impair our pricing and thereby constrain our market share and growth. In addition, we believe the increasing emphasis on managed care in the United States could put pressure on the price and usage of our product candidates, which may in turn adversely impact future product sales.

Significant uncertainty exists as to the reimbursement status of newly approved health care products, particularly for indications for which there is no current effective treatment or for which medical care typically is not sought. Adequate third-party coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If adequate coverage and reimbursement levels are not provided by government and third-party payors for use of our products, our products may fail to achieve market acceptance and we could lose anticipated revenues and experience delayed achievement of profitability.

In recent years, various legislative proposals have been offered in the United States Congress and in some state legislatures that include major changes in the health care system. These proposals have included price or patient reimbursement constraints on medicines and restrictions on access to certain products. We cannot predict the outcome of such initiatives, and it is difficult to predict the future impact of the broad and expanding legislative and regulatory requirements affecting us.

The European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. A member state may approve a specific price or level of reimbursement for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We will need to engage with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required in each European country for Cinryze, Buccolam and Plenadren and may not achieve the level of reimbursement anticipated or in the timeframes we anticipate, which could result in lower revenues than we anticipate in certain EU countries.

We rely on our employees, consultants, contractors, suppliers, manufacturers and collaborators to keep our trade secrets confidential.

We rely on trade secrets, trademarks, and unpatented proprietary know-how and continuing technological innovation in developing and manufacturing our products in order to protect our significant investment in these products from the risk of discovery by generic drug manufacturers and other potential competition. We require each of our employees, consultants, advisors, contractors, suppliers, manufacturers and collaborators to enter into confidentiality agreements prohibiting them from taking our proprietary information and technology or from using or disclosing proprietary information to third parties except in specified circumstances. The agreements also provide that all inventions conceived by an employee, consultant or advisor, to the extent appropriate for the services provided during the course of the relationship, are our exclusive property, other than inventions unrelated to us and developed entirely on the individual's own time. Nevertheless, these agreements may not provide meaningful protection of our trade secrets and proprietary know-how if they are used or disclosed. Despite all of the precautions we may take, people who are not parties to confidentiality agreements may obtain access to our trade secrets or know-how. In addition, others may independently develop similar or equivalent trade secrets or know-how.

We depend on patents and proprietary rights for our products which are in clinical development, which may offer only limited protection against potential infringement, and if we are unable to protect our patents and proprietary rights, we may lose the right to develop, manufacture, market or sell products and lose sources of revenue.

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success depends, in part, on our ability to develop and maintain a strong patent position for our products and technologies in clinical development, both in the United States and in other countries. Litigation or other legal proceedings may be necessary to defend against claims of infringement, to enforce our patents, or to protect our trade secrets, and could result in substantial cost to us and diversion of our efforts. We intend to file applications as appropriate for patents describing the composition of matter of our drug candidates, the proprietary processes for producing such compositions, and the uses of our drug candidates. We own three issued United States patents, one non- United States patents and have a number of pending United States patent applications, some of which we co-own with collaborators. We also have filed international, regional and non- United States national patent applications in order to pursue patent protection in major foreign countries.

Many of our scientific and management personnel were previously employed by competing companies. As a result, such companies may allege trade secret violations and similar claims against us.

To facilitate development of our proprietary technology base, we may need to obtain licenses to patents or other proprietary rights from other parties. If we are unable to obtain such licenses, our product development efforts may be delayed. We may collaborate with universities and governmental research organizations which, as a result, may acquire certain rights to any inventions or technical information derived from such collaboration.

We may incur substantial costs in asserting any patent rights and in defending suits against us related to intellectual property rights, even if we are ultimately successful. If we are unsuccessful in defending a claim that we have infringed or misappropriated the intellectual property of a third party, we could be required to pay substantial damages, stop using the disputed technology, develop new non-infringing technologies, or obtain one or more licenses from third parties. If we or our licensors seek to enforce our patents, a court may determine that our patents or our licensors' patents are invalid or unenforceable, or that the defendant's activity is not covered by the scope of our patents or our licensors' patents. The United States Patent and Trademark Office or a private party could institute an interference proceeding relating to our patents or patent applications. An opposition or revocation proceeding could be instituted in the patent offices of foreign jurisdictions. An adverse decision in any such proceeding could result in the loss of our rights to a patent or invention.

If our licensors do not protect our rights under our license agreements with them or do not reasonably consent to our sublicense of rights or if these license agreements are terminated, we may lose revenue and expend significant resources defending our rights.

We have licensed from GSK worldwide rights, excluding Japan, to an antiviral compound, maribavir, for the prevention and treatment of CMV infections related to transplant. This compound and a related compound are subject to patents and patent applications in a variety of countries throughout the world. We depend on GSK to prosecute and maintain many of these patents and patent applications and protect such patent rights. Failure by GSK to prosecute or maintain such patents or patent applications and protect such patent rights could lead to our loss of future revenue. Under certain circumstances, our ability to sublicense our rights under these license agreements is subject to the licensor's consent. If our license agreement with GSK is terminated, our ability to manufacture, develop, market and sell products under those agreements would terminate.

In September 2011, we entered into an exclusive license agreement with INS under which INS has granted us exclusive worldwide rights to develop, manufacture, distribute, market and sell products containing indole-3-propionic acid, or VP-20629. We intend to develop a licensed product containing VP-20629 for the treatment of Friedreich's Ataxia.

We depend on key personnel and may not be able to retain these employees or recruit additional qualified personnel, which would harm our ability to compete.

We are highly dependent upon qualified scientific, technical and managerial personnel, including our President and CEO, Vincent J. Milano, our Vice President, Chief Operating Officer, Daniel B. Soland, our Vice President, Chief Financial Officer, Charles Rowland, our Vice President, Chief Scientific Officer, Colin Broom, our Vice President, Global Regulatory Affairs and Quality, Robert Pietrusko and our Vice President, Strategic Initiatives, Thomas Doyle. Our ability to grow and expand into new areas and activities will require additional expertise and the addition of new qualified personnel in the United States, Europe and other markets. There is intense competition for qualified personnel in the pharmaceutical field. Therefore, we may not be able to attract and retain the qualified personnel necessary for the development of our business. Furthermore, we have not entered into non-competition agreements or employment agreements with our key employees. The loss of the services of existing personnel, as well as the failure to recruit additional key scientific, technical and managerial personnel in a timely manner, would harm our development programs, and our ability to manage day-to-day operations, attract collaboration partners, attract and retain other employees and generate revenues. We do not maintain key man life insurance on any of our employees.

Even after regulatory approval is received, as with Vancocin and Cinryze, if we fail to comply with regulatory requirements, or if we experience unanticipated problems with our approved products, they could be subject to restrictions or withdrawal from the market.

Cinryze and Vancocin are, and any other product for which we obtain marketing approval from the FDA or other regulatory authority will be, subject to continual review and periodic inspection by the FDA and other regulatory bodies. After approval of a product, we will have, and with Cinryze and Vancocin, we currently have, significant ongoing regulatory compliance obligations related to manufacturing processes, quality control, labeling, post-approval clinical data collection and promotional activities for each such product. Later discovery of previously unknown problems with our products or manufacturing processes, or failure to comply with regulatory requirements, may result in penalties or other actions, including:

- warning letters;
- class restrictions or “black-box” warnings
- fines;
- product recalls;
- withdrawal of regulatory approval;
- operating restrictions, including restrictions on such products or manufacturing processes;
- disgorgement of profits;
- injunctions; and
- criminal prosecution.

As part of the approval for Cinryze, we are required to conduct a clinical study designed to evaluate safety, including thrombotic adverse events, efficacy and immunogenicity of higher than 1000 Units doses of Cinryze every three or four days for routine prophylaxis. Collection and periodic reporting of CMC data also have been requested as a post-approval commitment. In the event we are unable to comply with these requirements and commitments, we may be subject to penalties or other actions. In addition, in June 2009, we received an untitled letter from the Office of Compliance and Biologics Quality in the FDA Center for Biologics Evaluation and Research alleging promotional materials were false or misleading because they present efficacy claims for Cinryze but failed to reveal, and they minimize, material facts; they make unsubstantiated comparative claims; and they overstate the efficacy of Cinryze. We have revised our marketing materials and the FDA has closed the review of these materials.

Over the past few years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities, including the DOJ and various United States Attorney’s Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the FTC and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the Food, Drug and Cosmetic Act, the False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with off-label promotion of products, pricing and Medicare and/or Medicaid reimbursement. It is both costly and time-consuming for us to comply with these extensive regulations to which it is subject. Additionally, incidents of adverse drug reactions, unintended side effects or misuse relating to our products could result in additional regulatory controls or restrictions, or even lead to withdrawal of a product from the market.

Companies may not promote drugs for “off-label” uses—that is, uses that are not described in the product’s labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician’s choice of treatments, the Federal Food, Drug and Cosmetics

Act and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of the Department of Health and Human Services (OIG) and FDA both actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the regulatory restrictions on off-label promotion, the OIG and the FDA allow companies to engage in truthful, non-misleading, and non-promotional speech concerning their products. Although we believe that all of our communications regarding all of our products are in compliance with the relevant legal requirements, the OIG or the FDA may disagree, and we may be subject to significant liability, including civil and administrative remedies, as well as criminal sanctions. In addition, management's attention could be diverted from our business operations and our reputation could be damaged.

The FDA provides guidelines with respect to appropriate promotion and continuing medical and health education activities. Although we endeavor to follow these guidelines, the FDA or the OIG may disagree, and we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. Should the government choose to initiate action against us, we could face substantial penalties, which could have a material adverse effect on our business, financial condition and results of operations. In addition, management's attention could be diverted and our reputation could be damaged.

In addition, anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, or pay any remuneration in exchange for purchasing, leasing or ordering any service or items including the purchase or prescription of a particular drug for which payment may be made under a federal health care program. Because of the sweeping language of the federal anti-kickback statute, many potentially beneficial business arrangements would be prohibited if the statute were strictly applied. To avoid this outcome, the United States Department of Health and Human Services has published regulations—known as “safe harbors”—that identify exceptions or exemptions to the statute's prohibitions. Arrangements that do not fit within the safe harbors are not automatically deemed to be illegal, but must be evaluated on a case-by-case basis for compliance with the statute. We seek to comply with anti-kickback statutes and to fit within one of the defined “safe harbors”. However, due to the breadth of the statutory provisions and the absence of uniform guidance in the form of regulations or court decisions, there can be no assurance that our practices will not be challenged under anti-kickback or similar laws. Violations of such restrictions may be punishable by civil and/or criminal sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from United States federal healthcare programs (including Medicaid and Medicare). Any such violations could have a material adverse effect on our business, financial condition and results of operations.

In recent years, several states and localities, including California, the District of Columbia, Maine, Massachusetts, Minnesota, Nevada, New Hampshire, New Mexico, Vermont, Texas, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation was approved by the federal government in 2010 and will take effect in 2012. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. If we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

Any of these events could result in a material adverse effect on our revenues and financial condition.

Our future product revenues from sales of Vancocin and Cinryze could be reduced by imports from countries where similar products are available at lower prices.

Vancocin has been approved for sale outside of the United States, including but not limited to Canada, Brazil and Europe, and Lilly or its licensees continue to market Vancocin outside of the United States. There are products

similar to Cinryze which are approved in the E.U. There have been cases in which pharmaceutical products were sold at steeply discounted prices in markets outside the United States and then imported to the United States where they could be resold at prices higher than the original discounted price, but lower than the prices commercially available in the United States. If this happens with Vancocin or Cinryze our revenues would be adversely affected. Additionally, there are non-United States, Internet-based companies supplying Vancocin directly to patients at significantly reduced prices.

In recent years, various legislative proposals have been offered in the United States Congress and in some state legislatures that would authorize re-importation of pharmaceutical products into the United States from other countries including Canada. We cannot predict the outcome of such initiatives, which if adopted, could result in increased competition for our products and lower prices.

Risks associated with our international business relationships could materially adversely affect our business.

We have employees located in Europe and are engaged in marketing and distributing several products, conducting clinical trials and have established manufacturing relationships in Europe. We have also established our own commercial sales and marketing personnel in Europe and plan to increase the number of personnel in certain European countries. In the future, we plan to expand our operations or enter into distribution arrangements with third parties to market our products and product candidates in countries outside of the United States and Europe. Consequently, we are, and will continue to be, subject to risks related to operating in foreign countries. Risks associated with conducting operations in foreign countries include:

- differing regulatory requirements for drug approvals in foreign countries;
- changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses or reduced revenues, and other obligations incident to doing business or operating a subsidiary in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

In Europe, we market two products that contain active ingredients that are controlled substances, and are therefore subject to additional regulation by European regulatory authorities relating to the procurement, manufacture, labeling, packaging, security controls, shipment, sale and use of these products. We continue to monitor economic conditions, including volatility associated with international economies, associated impacts on the financial markets and our business, and the sovereign debt crisis in Europe. The credit and economic conditions in Greece, Italy, Spain, Ireland and Portugal, among other members of the European Union have deteriorated throughout 2011. These conditions have resulted in, and may continue to result in, an increase in the average length of time it takes to collect our outstanding accounts receivable in these countries. We currently do not have any receivables in Greece, Italy, Spain or Portugal but anticipate that sales in one or more of these countries may commence during. In addition, incidents of product misuse, product diversion or theft may occur with products containing controlled substances. These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

If we are not successful in integrating recent additions to our clinical development pipeline into our business, then the benefits of the transactions will not be fully realized and the market price of our common stock may be negatively affected.

We have recently completed several business development transactions, including licensing VP-20629 from INS and acquiring DuoCort Pharmaceuticals. We may not achieve successful integration of these assets in a timely manner, or at all, and we may not realize the benefits acquisition to the extent, or in the timeframe, anticipated. The successful integration of these assets will require, among other things, integration of the VP-20629 asset into our preclinical and clinical development operations and integration of Plenadren into our European operations. It is possible that the integration process could result in the loss of key employees, diversion of our management's attention, the disruption or interruption of, or the loss of momentum in our ongoing business or inconsistencies in standards, controls, procedures and policies, any of which could adversely affect our ability to maintain relationships with customers, suppliers and employees or our ability to achieve the anticipated benefits of the acquisition, or could reduce our earnings or otherwise adversely affect our business and financial results as a result, adversely affect the market price of we common stock.

Charges to earnings resulting from the application of accounting methods may adversely affect the market value of our common stock as a result of the acquisition of DuoCort.

In accordance with Statement of Financial Accounting Standard No. 141R, Business Combinations, the total initial purchase price is allocated to DuoCort's net tangible assets or identifiable intangible assets based on their fair values as of the date of completion of the merger. We will incur additional amortization expense based on the identifiable amortizable intangible assets acquired pursuant to the merger agreement and their relative useful lives. These amortization charges will have a material impact on our results of operations, and therefore could have an adverse impact on the market value of our common stock.

Our indebtedness and other financial obligations may harm our financial condition and results of operations.

Our total consolidated long-term debt as of December 31, 2011 is \$205.0 million. Additionally, we have unused availability under the three-year senior secured revolving credit facility of up to \$200.0 million. Our level of indebtedness could have important consequences to you, because:

- a portion of our cash flows from operations will have to be dedicated to interest and may not be available for operations, working capital, capital expenditures, expansion, acquisitions or general corporate or other purposes;
- it may impair our ability to obtain additional financing in the future;
- it may limit our flexibility in planning for, or reacting to, changes in our business and industry; and
- it may make us more vulnerable to downturns in our business, our industry or the economy in general.

Our operations may not generate sufficient cash to enable us to service our debt. If we fail to make a payment on the senior convertible notes, we could be in default on the senior convertible notes, and this default could cause us to be in default on our other outstanding indebtedness. Conversely, a default on our other outstanding indebtedness may cause a default under the senior convertible notes.

We have a future liability in the form of a contingent value payments to the former stockholders of Lev upon the achievement of a commercial target. The CVR payment of \$0.50 per share (\$87.5 million) would become payable when Cinryze reaches at least \$600 million in cumulative net product sales within 10 years of closing of the acquisition. We anticipate that this payment will be payable during 2012. In addition, we have a future liability in the form of contingent milestone payments to the former stockholders of DuoCort. Payments of up to 860 million SEK or approximately \$124 million would become payable upon the achievement of certain milestones related to Plenadren manufacturing, sales and territory expansion. We cannot predict if or when these payments may be payable or if they could materially adversely affect our business at the time of payment.

Covenants in our debt agreements restrict our business in several ways.

The agreements governing our outstanding indebtedness subject us to various covenants that limit our ability and/or our restricted subsidiaries' ability to, among other things:

- incur or assume liens or additional debt or provide guarantees in respect of obligations of other persons;
- pay dividends or distributions or redeem or repurchase capital stock;
- prepay, redeem or repurchase debt;
- make loans, investments and capital expenditures;
- enter into agreements that restrict distributions from our subsidiaries;
- sell assets and capital stock of our subsidiaries;
- enter into certain transactions with affiliates; and
- consolidate or merge with or into, or sell substantially all of our assets to, another person.

A breach of any of these covenants could result in a default under our indebtedness.

Our failure to comply with the agreements relating to our outstanding indebtedness, including as a result of events beyond our control, could result in a default under our outstanding indebtedness that could materially and adversely affect our results of operations and our financial condition.

If there were an event of default under any of the agreements relating to our outstanding indebtedness, the holders of the defaulted debt could cause all amounts outstanding with respect to that debt to be due and payable immediately and our lenders could terminate all commitments to extend further credit. The instruments governing our debt contain cross-default or cross-acceleration provisions that may cause all of the debt issued under such instruments to become immediately due and payable as a result of a default under an unrelated debt instrument. An event of default or an acceleration under one debt agreement could cause a cross-default or cross-acceleration of other debt agreements. We cannot assure you that our assets or cash flow would be sufficient to fully repay borrowings under our outstanding debt instruments if the obligations thereunder are accelerated upon an event of default. Further, if we are unable to repay, refinance or restructure our secured debt, the holders of such debt could proceed against the collateral securing that indebtedness. We have pledged substantially all of our assets as collateral under our Credit Facility. If the lenders under our Credit Facility accelerate the repayment of borrowings, we may not have sufficient assets to repay the obligations outstanding under our Credit Facility and our other indebtedness, including the Senior Notes.

Our stock price could continue to be volatile.

Our stock price, like the market price of the stock of other pharmaceutical companies, has been volatile. For example, during the twelve months ended December 31, 2011, the market price for our common stock fluctuated between \$14.62 and \$28.34 per share. The following factors, among others, could have a significant impact on the market for our common stock:

- period to period fluctuations in sales of Vancocin and Cinryze;
- approvals of generic products that compete with Vancocin;
- our ability to successfully manufacture sufficient amounts of Cinryze to meet demand and increase manufacturing capacity;
- results of clinical trials with respect to our product candidates in development or those of our competitors;
- developments with our collaborators;

- announcements of technological innovations or new products by our competitors;
- litigation or public concern relating to our products or our competitors' products;
- developments in patent or other proprietary rights of our or its competitors (including related litigation);
- any announcement regarding our acquisition of product candidates or entities;
- future announcements concerning our industry;
- governmental regulation;
- changes in federal, state and foreign tax laws and related regulations;
- actions or decisions by the SEC, the FDA, the EMA or other regulatory agencies;
- changes or announcements of changes in reimbursement policies;
- period to period fluctuations in our operating results, including changes in accounting estimates;
- our cash and cash equivalents balances;
- changes in our capital structure;
- changes in estimates of our performance by securities analysts;
- market conditions applicable to our business sector; and
- general market conditions.

The rights that have been and may in the future be granted to holders of our common or preferred stock may adversely affect the rights of other stockholders and may discourage a takeover.

Our board of directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the price, privileges and other terms of such shares. Our board of directors may exercise this authority without the approval of, or notice to, our stockholders. Accordingly, the rights of the holders of our common stock may be adversely affected by the rights of the holders of any preferred stock that may be issued in the future. In addition, the issuance of preferred stock may make it more difficult for a third party to acquire a majority of our outstanding voting stock in order to effect a change in control or replace our current management. We are also subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. The application of Section 203 could also delay or prevent a third party or a significant stockholder of ours from acquiring control of us or replacing its current management. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder, unless the business combination or the transaction in which the person became an interested stockholder is approved in a prescribed manner. Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. Under Delaware law, an interested stockholder is a person who, together with affiliates and associates, owns 15% or more of a corporation's voting stock.

In addition, our charter and bylaws contain certain provisions that could discourage a hostile takeover, such as a staggered board of directors and significant notice provisions for nominations of directors and proposals. Our charter and bylaws may make it more difficult for a third party to acquire a majority of our outstanding voting stock in order to effect a change in control or replace our current management.

Conversion of the senior convertible senior notes will dilute the ownership interest of existing stockholders.

To the extent we issue any shares of our common stock upon conversion of the senior convertible senior notes, the conversion of some or all of the senior convertible senior notes will dilute the ownership interests of existing

stockholders. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the senior convertible senior notes may encourage short selling by market participants because the conversion of the senior convertible senior notes could depress the price of our common stock.

The convertible note hedge and warrant transactions may affect the value of our common stock and other securities, and expose us to counterparty risk.

In connection with the issuance of the senior convertible senior notes, we have entered into privately-negotiated convertible note hedge transactions with two counterparties, which are expected to generally reduce the potential equity dilution of our common stock upon conversion of the senior convertible notes. To reduce the cost to us of the convertible note hedge transactions, we also entered into warrant transactions with these counterparties. To the extent that the price of our common stock exceeds the exercise price of the warrant transactions, the warrant transactions will be dilutive to us.

In connection with establishing their initial hedge of these transactions, the counterparties (and/or their affiliates) may have entered into various derivative transactions with respect to our common stock. The counterparties (and/or their affiliates) may modify their hedge positions from time to time by entering into or unwinding various derivative transactions with respect to our common stock or by purchasing or selling our common stock or other securities in secondary market transactions, which could adversely affect the value of our common stock or such securities, or could have the effect of increasing or preventing a decline in the value of our common stock or such securities. We are exposed to counterparty credit risk to the extent that the counterparties do not satisfy their obligations under the convertible note hedge transactions. We will be required to perform in full our obligations under the warrant transactions, regardless of whether the counterparties perform, in whole or in part, their obligations under the convertible note hedge transactions.

The potential effect, if any, of any of these transactions and activities on the market price of our common stock and other securities will depend in part on market conditions, and cannot be ascertained at this time.

The fundamental change purchase feature of the senior convertible notes may delay or prevent an otherwise beneficial attempt to take over our company.

The terms of the senior convertible notes require us to purchase the senior convertible notes for cash in the event of a fundamental change. A takeover of our company would trigger the requirement that we purchase the senior convertible notes. Alternatively, if certain transactions that constitute a fundamental change occur, under certain circumstances, we will increase the conversion rate by a number of additional shares of our common stock to compensate holders for the lost option time value of the senior convertible notes as a result of such transaction. This increased conversion rate will apply only to holders who convert their senior convertible notes in connection with any such transaction. The number of the additional shares of our common stock will be determined based on the date on which the transaction becomes effective and the price paid per share of our common stock. This may have the effect of delaying or preventing a takeover of our company that would otherwise be beneficial to investors.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

In March 2008, we entered into a lease, comprising 78,264 square feet of office and related space, for the Company's headquarters located in Exton, Pennsylvania. The lease expires in April 2015.

In May 2008, we entered into a lease in Maidenhead, United Kingdom, comprising 8,000 square feet of office space, for our U.K. operations. The lease expires in May 2018.

We also lease office space for our European operations in Belgium, Germany, Italy, France, Spain, Sweden and Canada and intend to lease additional office space in additional countries as we establish operations in those countries.

On January 30, 2007, we purchased 33,000 square feet facility located in Exton, PA. We vacated this space in October 2008 when we moved into our new headquarters. In October 2009, we leased this facility to a third party for an initial term of five years.

ITEM 3. LEGAL PROCEEDINGS

On May 26, 2011, we filed a notice of appeal to the United States Court of Appeals for the District of Columbia Circuit from the final order granting a motion to dismiss the Company's motion for declaratory relief (the "Complaint") against the Food and Drug Administration, Margaret A. Hamburg, M.D., in her official capacity as Commissioner of Food and Drug Administration, the United States Department of Health and Human Services ("HHS"), and Kathleen Sebelius, in her official capacity as Secretary of HHS, (collectively "FDA") entered in the United States District Court for the District of Columbia (the "District Court") on April 15, 2011. Pursuant to the Complaint, we sought review under the Administrative Procedure Act ("APA") of the FDA's decision to change its regulations to abandon its longstanding rule that an applicant for an Abbreviated New Drug Application ("ANDA") seeking to demonstrate bioequivalence must do so through *in vivo* evidence unless the applicant obtains a waiver pursuant to the enumerated waiver criteria set forth in 21 C.F.R. § 320.22. We had requested that the Court determine that (i) the plain reading of FDA's regulations requires *in vivo* bioequivalence testing unless one of the criteria set forth in 21 C.F.R. § 320.22 is satisfied, and (ii) FDA's amendment of its regulations governing waiver of submission of *in vivo* bioequivalence evidence, without notice-and-comment rulemaking, violates 5 U.S.C. § 553 of the APA and was therefore invalid. The District Court did not address these arguments but instead granted the motion to dismiss brought by the defendants on a basis of a lack of standing. On October 6, 2011, we filed a brief with the United States Court of Appeals for the District of Columbia Circuit.

From time to time we are a party to litigation in the ordinary course of our business. We do not believe these matters, even if adversely adjudicated or settled, would have a material adverse effect on our financial condition, results of operations or cash flows.

ITEM 4. Mine Safety Disclosures

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded on the Global Market segment of The NASDAQ Stock Market under the symbol "VPHM." We commenced trading on The NASDAQ Stock Market on November 19, 1996. The following table sets forth the high and low sale prices as quoted on The NASDAQ Stock Market for each quarter of 2010 and 2011 and through February 15, 2012.

	<u>High</u>	<u>Low</u>
Year ended December 31, 2010		
First Quarter	\$14.40	\$ 8.41
Second Quarter	\$14.33	\$10.78
Third Quarter	\$15.45	\$10.29
Fourth Quarter	\$18.37	\$14.28
Year ended December 31, 2011		
First Quarter	\$20.28	\$15.80
Second Quarter	\$22.16	\$17.21
Third Quarter	\$20.34	\$14.62
Fourth Quarter	\$28.34	\$17.25
First Quarter 2012 (through February 15, 2012)	\$31.99	\$27.41

Holders and Dividends

There were approximately 562 record holders of our common stock as of February 15, 2012. We have never declared or paid any cash dividends on our common stock. We have declared and paid dividends in the past on our previously outstanding Series A convertible participating preferred stock. As of February 28, 2012, we had no shares of preferred stock outstanding. Any future determination to pay dividends will be at the discretion of our board of directors and will be dependent on then existing conditions, including our financial condition, results of operations, contractual restrictions, capital requirements, business and other factors our board of directors deems relevant.

Issuer Purchases of Equity Securities

Below is a summary of stock repurchases for the three months ended December 31, 2011:

<u>Month</u>	<u>Total Number of Shares Purchased(1)</u>	<u>Average Price Paid per Share(2)</u>	<u>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</u>	<u>Approximate Dollar Value of Shares that May Yet Be Purchased under the Plans or Programs (in thousands)(1)(3)</u>
October 1 – October 31	—	\$ —	—	\$201,115,508
November 1 – November 30	1,007,500	\$20.62	1,007,500	\$180,339,421
December 1 – December 31	—	\$ —	—	\$180,339,421
Total	<u>1,007,500</u>	<u>\$20.62</u>	<u>1,007,500</u>	

- (1) In September 2011, our Board of Directors authorized up to \$200.0 million for repurchases of ViroPharma Incorporated's outstanding shares of common stock or 2% senior convertible notes due 2017. The \$200.0 million authorization authorizes management to repurchase shares in the open market, in block transactions, in private transactions or other techniques from time to time, depending on market conditions.

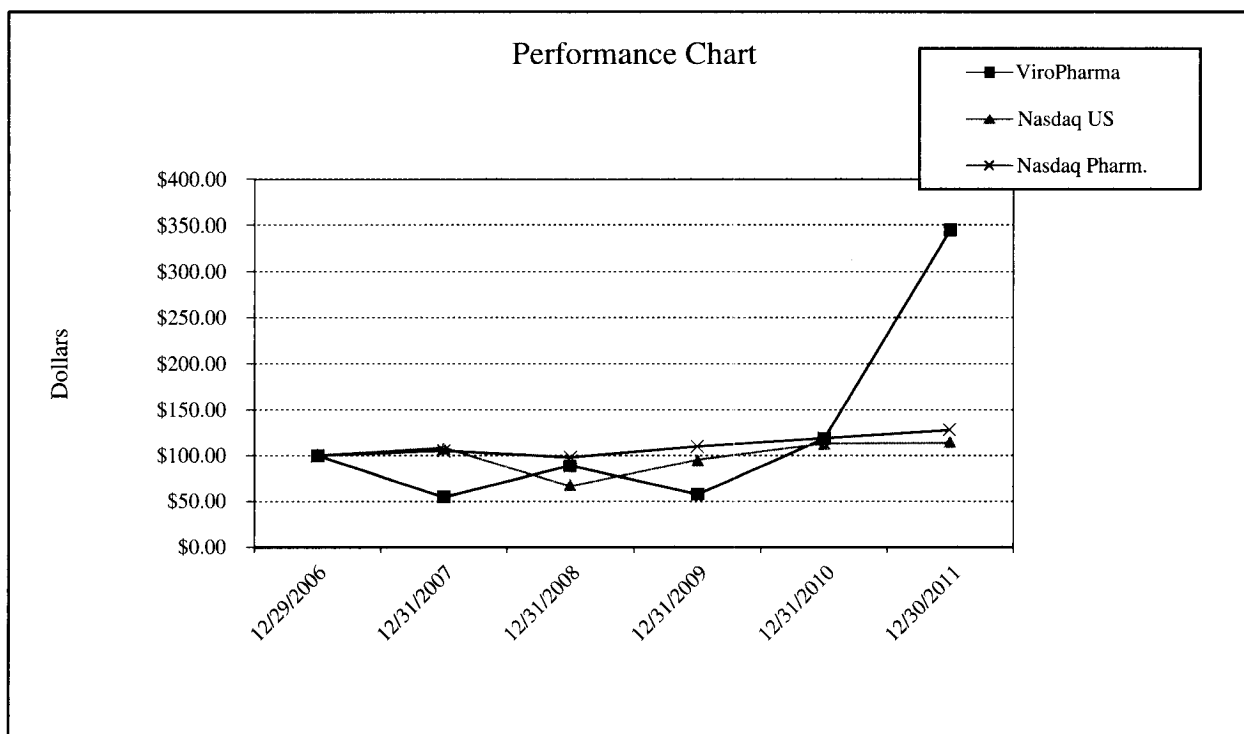
During the fourth quarter of 2011, through open market purchases, we reacquired approximately 1.0 million shares at a cost of approximately \$20.8 million or an average price of \$20.62 per share. In March 2011, our Board of Directors authorized up to \$150.0 million for repurchases of ViroPharma Incorporated's outstanding shares of common stock or 2% senior convertible notes due 2017. Purchase completed during the first three quarters of 2011 effectively completed our repurchases program authorized by our board on March 9, 2011.

- (2) The Average Price Paid per Share is based on the price paid per share in the open market. The average price was determined based on the volume weighted-average-price of our stock during the day the repurchases had occurred.

During the period covered by this report, we did not sell any of our equity shares that were not registered under the Securities Act of 1933, as amended.

Performance Graph

The following graph compares the cumulative five-year total return on our common stock relative to the cumulative total returns of the NASDAQ Composite Index and the NASDAQ Pharmaceutical Index. An investment of \$100 (with reinvestment of all dividends) is assumed to have been made in our common stock and in each of the indexes on December 31, 2006 and its relative performance is tracked through December 31, 2011.



	As of December 31,					
	2006	2007	2008	2009	2010	2011
ViroPharma Incorporated	100.00	54.23	88.93	57.31	118.31	344.96
NASDAQ Composite Index	100.00	108.50	66.35	95.38	113.19	113.81
NASDAQ Pharmaceutical Index	100.00	105.17	97.85	109.95	119.19	127.71

The stock price performance included in this graph is not necessarily indicative of future stock price performance.

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data presented below under the caption “Consolidated Statement of Operations Data” for the years ended December 31, 2011, 2010, 2009, 2008, and 2007 and under the caption “Consolidated Balance Sheet Data” as of December 31, 2011, 2010, 2009, 2008, and 2007 are derived from our consolidated financial statements which have been audited. The data set forth below should be read in conjunction with Management’s Discussion and Analysis of Financial Condition and Results of Operations, the Consolidated Financial Statements and the notes thereto and the other financial information included elsewhere in this Report.

In October 2008, we acquired Lev Pharmaceuticals, Inc., in May 2010 we acquired Auralis Limited and in November 2011 we acquired DuoCort Pharma AB.

(in thousands, except per share amounts)	Year Ended December 31,				
	2011	2010	2009	2008	2007
Consolidated Statement of Operations Data:					
Net product sales	\$ 544,374	\$ 439,012	\$ 310,449	\$ 232,307	\$203,770
Operating expenses:					
Cost of sales (excluding amortization of product rights)	79,976	61,288	40,214	8,874	8,934
Research and development	66,477	39,613	52,083	64,434	33,925
Selling, general and administrative	127,775	95,664	89,316	67,270	38,995
Intangible amortization and acquisition of technology rights	31,035	29,357	28,183	10,809	6,120
Goodwill impairment	—	—	65,099	—	—
Impairment loss	8,495	—	3,424	2,265	—
Other operating expenses	8,488	1,390	—	—	—
Total operating expenses	322,246	227,312	278,319	153,652	87,974
Operating income	222,128	211,700	32,130	78,655	115,796
Interest income	655	372	352	14,296	24,265
Interest expense	(12,640)	(11,616)	(11,609)	(12,951)	(9,612)
Other (expense) income, net	(2,136)	430	—	—	—
Gain on long-term debt repurchase	—	—	9,079	—	—
Income tax expense	67,348	75,278	41,029	16,040	38,344
Net income (loss)	\$ 140,659	\$ 125,608	\$ (11,077)	\$ 63,960	\$ 92,105
Net income (loss) per share:					
Basic	\$ 1.89	\$ 1.61	\$ (0.14)	\$ 0.90	\$ 1.32
Diluted	\$ 1.68	\$ 1.47	\$ (0.14)	\$ 0.84	\$ 1.21
Shares used in computing net income (loss) per share:					
Basic	74,517	77,820	77,423	71,391	69,827
Diluted	88,076	90,081	77,423	85,712	80,891
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investments	\$ 459,830	\$ 505,171	\$ 331,672	\$ 275,839	\$584,328
Working capital	537,280	561,019	406,375	317,413	596,819
Total assets	1,336,797	1,287,574	1,084,451	1,086,129	771,605
Long-term debt	153,453	145,743	138,614	161,003	153,572
Total stockholders’ equity	891,124	891,135	750,387	749,334	558,530

We have never paid dividends on our common stock.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Background

ViroPharma Incorporated is a global biotechnology company dedicated to the development and commercialization of products that address serious diseases, with a focus on products used by physician specialists or in hospital settings. We intend to grow through sales of our marketed products, through continued development of our product pipeline, expansion of sales into additional territories outside the United States, through potential acquisition or licensing of products and product candidates and the acquisition of companies. We expect future growth to be driven by sales of Vancocin, sales of Cinryze, both domestically and internationally, sales of Buccolam and Plenadren in Europe, and by our primary development programs, including C1 esterase inhibitor and a non-toxigenic strain of *C. difficile* (VP20621).

We market and sell Cinryze in the United States for routine prophylaxis against angioedema attacks in adolescent and adult patients with hereditary angioedema (HAE). Cinryze is a C1 esterase inhibitor therapy for routine prophylaxis against HAE, also known as C1 inhibitor (C1-INH) deficiency, a rare, severely debilitating, life-threatening genetic disorder. Cinryze was acquired in October 2008 and in January 2010, we acquired expanded rights to commercialize Cinryze and future C1-INH derived products in certain European countries and other territories throughout the world as well as rights to develop future C1-INH derived products for additional indications. In June 2011, the European Commission granted us Centralized Marketing Authorization for Cinryze® in adults and adolescents with HAE for routine prevention, pre-procedure prevention and acute treatment of angioedema attacks. The approval also includes a self administration option for appropriately trained patients. We have begun to commercialize Cinryze in Europe and continue to evaluate our commercialization plans in countries where we have distribution rights.

We also market and sell Vancocin HCl capsules, the oral capsule formulation of vancomycin hydrochloride, in the U.S. and its territories. Vancocin is indicated for the treatment of *C. difficile*-associated diarrhea (CDAD). Vancocin capsules are also used for the treatment of enterocolitis caused by *Staphylococcus aureus*, including methicillin-resistant strains.

On December 14, 2011, we announced the modernization of labeling for Vancocin capsules made effective through the FDA's approval of a supplemental new drug application (sNDA).

On November 15, 2011, we acquired a 100% ownership interest in DuoCort Pharma AB (DuoCort), a private company based in Helsingborg, Sweden focused on improving glucocorticoid replacement therapy for treatment of adrenal insufficiency, or Addison's disease (AD). We paid approximately 213 million Swedish Krona (SEK) or approximately \$32.1 million in upfront consideration. We have also agreed to make additional payments ranging from SEK 240 million up to SEK 860 million or approximately \$35 million to \$124 million, contingent on the achievement of certain milestones. Up to SEK 160 million or approximately \$23 million of the contingent payments relate to specific regulatory milestones; and up to SEK 700 million or approximately \$101 million of the contingent payments are related to commercial milestones based on the success of the product.

As part of the closing of this transaction, we also paid approximately SEK 9.3 million or \$1.4 million to certain of DuoCort's creditors. We incurred approximately \$1.4 million of transaction cost as part of this acquisition.

The acquisition of Duocort further expands our orphan disease commercial product portfolio. On November 3, 2011, the European Commission (EC) granted European Marketing Authorization for Plenadren® (hydrocortisone, modified release tablet), an orphan drug for treatment of adrenal insufficiency in adults, which will bring these patients their first pharmaceutical innovation in over 50 years. We anticipate commercial launch of Plenadren in the EU in late 2012 or early 2013. A named patient program is currently available to patients in Europe, which we expect to continue until commercial launch.

In May 2010, we acquired Auralis Limited, a UK based specialty pharmaceutical company. The acquisition of Auralis provides us with the opportunity to accelerate our European commercial systems for potential future product launches and additional business development acquisitions. In connection with the Auralis acquisition, we acquired Buccolam® (Oromucosal Solution, Midazolam [as hydrochloride]). In September of 2011, the European Commission granted a Centralized Pediatric Use Marketing Authorization (PUMA) for Buccolam, for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from 3 months to less than 18 years of age. We have begun to commercialize Buccolam in Europe.

Our product development portfolio is primarily focused on three programs, C1 esterase inhibitor [human], VP20621 and VP-20629.

We are working on developing further therapeutic uses, potential additional indications in other C1 mediated diseases, and alternative modes of administration for C1 esterase inhibitor. We are currently undertaking studies on the viability of subcutaneous administration of Cinryze. We intend to conduct ViroPharma sponsored studies and investigator-initiated studies (IIS) to identify further therapeutic uses and potentially expand the labeled indication for Cinryze to include other C1 mediated diseases. We are also conducting our own studies of Cinryze in Antibody-Mediated Rejection (AMR) and Delayed Graft Function (DGF). Additionally, in May 2011, Halozyme Therapeutics (Halozyme) granted us an exclusive worldwide license to use Halozyme's proprietary Enhance™ technology, a proprietary drug delivery platform using Halozyme's recombinant human hyaluronidase enzyme (rHuPH20) technology in combination with a C1 esterase inhibitor. We intend to apply rHuPH20 initially to develop an alternative subcutaneous formulation of Cinryze for routine prophylaxis against attacks of HAE. In September 2011, we initiated a Phase 2 study to evaluate the safety, and pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20.

We are also developing VP20621 for the treatment and prevention of CDAD. In May 2011, we initiated a Phase 2 dose-ranging clinical study to evaluate the safety, tolerability, and efficacy of VP 20621 for prevention of recurrence of CDAD in adults previously treated for CDAD.

On September 30, 2011, we entered into a license agreement for the worldwide rights of Intellect Neurosciences, Inc. (INS) to its clinical stage drug candidate, VP-20629, which we expect to develop for the treatment of Friedreich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease. VP-20629, or indole-3-propionic acid, is a naturally occurring, small molecule that has potent anti-oxidant properties that can protect against neurodegenerative disease. In a recent Phase 1 safety and tolerability study conducted in the Netherlands, VP-20629 was demonstrated to be safe and well tolerated at all dose levels tested. We expect to initiate a phase 2 study within 12 to 18 months of the date of this agreement, after completion of longer-term toxicology studies. We intend to file for Orphan Drug Designation upon review of the phase 2 proof of concept data.

Under the terms of the agreement, we have exclusive worldwide rights to develop and commercialize VP-20629 for the treatment, management or prevention of any disease or condition covered by Intellect's patents. We paid INS a \$6.5 million up-front licensing fee and may pay additional milestones up to \$120 million based upon defined events. We will also pay a tiered royalty of up to a maximum percentage of low teens, based on annual net sales.

In addition to these programs, we have several other assets that we may make additional investments in. These investments will be limited and dependent on our assessment of the potential future commercial success of or benefits from the asset. These assets include maribavir for CMV, recombinant C1-INH and other compounds.

On December 22, 2011, we entered into an exclusive development and option agreement with Meritage Pharma, Inc. (Meritage), a private company based in San Diego, CA focused on developing oral budesonide suspension (OBS) as a treatment for eosinophilic esophagitis (EoE). EoE is a newly recognized chronic disease that is increasingly being diagnosed in children and adults. It is characterized by inflammation and accumulation of a

specific type of immune cell, called an eosinophil, in the esophagus. EoE patients may have persistent or relapsing symptoms, which include dysphagia (difficulty in swallowing), nausea, stomach pain, chest pain, heartburn, loss of weight and food impaction.

We have an exclusive option to acquire Meritage, at our sole discretion, by providing written notice at any time during the period from December 22, 2011 to and including the date that is the earlier of (a) the date that is 30 business days after the later of (i) the receipt of the final study data for the Phase 2 study and (ii) identification of an acceptable clinical end point definition for a pivotal induction study agreed to by the FDA. As consideration for the option, we paid an initial \$7.5 million and have the option to provide Meritage up to an additional \$12.5 million for the development of OBS. Meritage will utilize the funding to conduct additional Phase 2 clinical assessment of OBS. If we exercise this option, we have agreed to pay \$69.9 million for all of the outstanding capital stock of Meritage. Meritage stockholders could also receive additional payments of up to \$175 million, upon the achievement of certain clinical and regulatory milestones.

We intend to continue to evaluate in-licensing or other opportunities to acquire products in development, or those that are currently on the market. We plan to seek products that treat serious or life threatening illnesses with a high unmet medical need, require limited commercial infrastructure to market, and which we believe will provide both revenue and earnings growth over time.

Executive Summary

Since December 31, 2010, we experienced the following:

Business Activities

Cinryze:

- Shipped approximately 64,000 doses of Cinryze to specialty pharmacy/specialty distributors (SP/SD's);
- The European Commission granted us Centralized Marketing Authorization for Cinryze in adults and adolescents with HAE for routine prevention, pre-procedure prevention and acute treatment of angioedema attacks and we began commercial sales of Cinryze in Europe in the fourth quarter of 2011;
- Announced a collaboration with Halozyme for combination of Halozyme's recombinant human hyaluronidase enzyme (rHuPH20) technology with a C1 esterase inhibitor and initiated a Phase 2 study to evaluate the safety, and pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20 from which we received positive top line data from the trial; and,
- Initiated a Phase 2 clinical study to evaluate the safety and efficacy of C1 Esterase Inhibitor [Human] for the treatment of acute antibody-mediated rejection (AMR) in recipients of donor-specific cross-match positive kidney transplants and withdrew Cinryze from the register of orphan medicinal products of the EMA;

C. difficile infection (CDAD):

- Announced the modernization of labeling for Vancocin capsules made effective through the FDA's approval of a supplemental new drug application (sNDA);
- Initiated a Phase 2 dose-ranging clinical study to evaluate the safety, tolerability, and efficacy of VP 20621 for prevention of recurrence of CDAD in adults previously treated for CDAD; and,
- Vancocin scripts decreased 5.6% in 2011 as compared to 2010;

Buccolam:

- Received a PUMA (Pediatric Use Marketing Authorization) for Buccolam from the European Commission and we began commercial sales of Buccolam in Europe in the fourth quarter of 2011;

Business Development:

- Entered into the INS license agreement;
- Acquired DuoCort; and,
- Entered into the development and option agreement with Meritage;

Financial Results

- Net sales of Cinryze increased to \$251.2 million for the year ended December 31, 2011 from \$176.8 million for the year ended December 31, 2010;
- Net sales of Vancocin increased to \$288.9 million for the year ended December 31, 2011 from \$259.6 million for the year ended December 31, 2010; and,
- Reported net income of \$140.7 million for the year ended December 31, 2011;

Liquidity

- Generated net cash from operations of \$170.7 million;
- Ended 2011 with working capital of \$537.3 million which includes cash and cash equivalents of \$331.4 million and investments of \$128.5 million;
- Entered into \$200 million revolving credit facility; and,
- Repurchased approximately 9.2 million shares of our common stock at a cost of approximately \$169.7 million

During 2012 and going forward, we expect to face a number of challenges, which include the following:

The commercial sale of approved pharmaceutical products is subject to risks and uncertainties. There can be no assurance that future Vancocin sales will meet or exceed the historical rate of sales for the product, for reasons that include, but are not limited to, generic and non-generic competition for Vancocin and/or changes in prescribing habits or disease incidence.

The FDA convened a meeting of its Advisory Committee for Pharmaceutical Science and Clinical Pharmacology to discuss bioequivalence recommendations for oral vancomycin hydrochloride capsule drug products on August 4, 2009. The Advisory Committee was asked if the proposed guidelines are sufficient for establishing bioequivalence for generic vancomycin oral capsules. The Advisory Committee voted unanimously in favor of the component of the proposed OGD recommendation that requires bioequivalence to be demonstrated through comparable dissolution in media of pH 1.2, 4.5 and 6.8 for potential vancomycin HCl capsule generic products that (a) contain the same active and inactive ingredients in the same amounts as Vancocin HCl capsules; (b) meet currently accepted standards for assay, potency, purity, and stability (equivalent to those in place for Vancocin HCl capsules); and (c) are manufactured according to cGMP. We have opposed both the substance of the FDA's bioequivalence method and the manner in which it was developed. There can be no assurance that the FDA will agree with the positions stated in our Vancocin related submissions or that our efforts to oppose the OGD's March 2006 and December 2008 recommendation to determine bioequivalence to Vancocin through in-vitro dissolution testing will be successful.

On December 14, 2011, we announced the modernization of labeling for Vancocin Capsules made effective through the FDA's approval of a supplemental new drug application (sNDA).

Through the sNDA approval, Vancocin's label for the first time includes clinical safety and efficacy data for the use of Vancocin capsules in treating *Clostridium difficile*. Vancocin's labeling now reflects safety and efficacy data from 260 patients with *C. difficile*-associated diarrhea (CDAD) treated with Vancocin in two pivotal studies

of Genzyme Corporation's investigational drug, tolevamer. We purchased exclusive rights to the two studies from Genzyme for which we will pay Genzyme royalties of 10 percent, 10 percent and 16 percent on net sales of Vancocin for the three year period following the approval of the sNDA.

As a result of the sNDA approval, we believe Vancocin meets the requirements for three years of exclusivity, and that generic vancomycin capsules will not be approved during this period. Under FDA's regulations, labeling changes based on new clinical investigations that are essential to approval of the sNDA and to which the applicant has exclusive rights may be entitled to three years of exclusivity, and generic drug labeling cannot include information protected by such three-year exclusivity. A generic may seek approval by omitting labeling protected by three-year exclusivity; however, if such omissions render the generic drug less safe or effective, it cannot be approved until the three-year exclusivity expires.

We believe that attempting to omit Vancocin labeling changes protected by exclusivity would render generic versions of Vancocin less safe and effective. However, ultimately, the decision on a grant of three-year exclusivity and its effect on generic vancomycin capsule approvals resides with the FDA.

We cannot predict the timeframe in which the FDA will make a decision regarding either our citizen petition for Vancocin or the approval of generic versions of Vancocin. If FDA's proposed bioequivalence method for Vancocin becomes effective, and either FDA does not agree that our labeling changes made effective through our sNDA warrant exclusivity, or FDA acknowledges such exclusivity but nonetheless determines that generic products would be no less safe or effective in the absence of such labeling changes, then the time period in which a generic competitor could be approved would be reduced and multiple generics may enter the market. The approval of generic copies of Vancocin would materially impact our operating results, cash flows and possibly intangible asset valuations. This could also result in a reduction to the useful life of the Vancocin-related intangible assets. Management currently believes there are no indicators that would require a change in useful life as management believes that Vancocin will continue to be utilized along with generics that may enter the market, and the number of generics and the timing of their market entry is unknown.

Approval of new products, or expanded use of currently available products, to treat CDAD, and particularly severe disease caused by *C. difficile* infection, could materially and adversely affect our sales of Vancocin. The number of units sold of Vancocin for the treatment of *C. difficile-associated diarrhea* has increased over the past 12 months but Vancocin's share of the U.S. market for this indication may decrease due to competitive forces and market dynamics. In May 2011, FDA approved Optimer Pharmaceuticals' product, Dificid® (fidaxomicin), for the treatment of CDAD. Metronidazole, a generic product, is regularly prescribed to treat CDAD at costs which are substantially lower than for Vancocin. Products which are currently marketed for other indications by other companies may also be prescribed to treat this indication. Additionally, several other companies, including, Merck & Co., Sanofi-Aventis and Cubist Pharmaceuticals have clinical development programs with therapeutic agents for the treatment of *C. difficile* infection that could be found to have competitive advantages over Vancocin.

The FDA approved Cinryze for routine prophylaxis against angioedema attacks in adolescent and adult patients with hereditary angioedema on October 10, 2008. Cinryze became commercially available for routine prophylaxis against HAE in December 2008. The commercial success of Cinryze depends on several factors, including: the number of patients with HAE that may be treated with Cinryze; manufacturing or supply interruptions and capacity which could impair our ability to acquire an adequate supply of Cinryze to meet demand for the product; and our ability to achieve expansion of manufacturing capabilities in the capacities and timeframes currently anticipated; acceptance by physicians and patients of Cinryze as a safe and effective treatment; our ability to effectively market and distribute Cinryze in the United States; cost effectiveness of HAE treatment using Cinryze; relative convenience and ease of administration of Cinryze; potential advantages of Cinryze over alternative treatments; the timing of the approval of competitive products including another C1 esterase inhibitor for the acute treatment of HAE; the market acceptance of competing approved products such as Berinert; patients' ability to obtain sufficient coverage or reimbursement by third-party payors; variations in

dosing arising from physician preferences and patient compliance; sufficient supply and reasonable pricing of raw materials necessary to manufacture Cinryze. In addition, our ability to develop life cycle management plans for Cinryze, including designing and commencing clinical studies for additional indications and pursuing regulatory approvals in additional indications or territories will impact our ability to generate future revenues from Cinryze. In Europe, the European Commission has granted us Centralized Marketing Authorization for Cinryze in adults and adolescents with HAE for routine prevention, pre-procedure prevention and acute treatment of angioedema attacks. The approval also includes a self administration option for appropriately trained patients. In addition, the European Commission has granted us a PUMA for Buccolam. We have begun the commercial sales of these products in Europe during the fourth quarter of 2011. The commercial success of each of these products in Europe will depend on a number of factors, including the impact of the loss of orphan designation on Cinryze, market acceptance of each of the products and our ability to manufacture sufficient quantities of product to meet patient needs.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA), which was amended by the Health Care and Education Reconciliation Act of 2010. PPACA, as amended, is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. Several provisions of the new law, which have varying effective dates, will affect us. These include new requirements on private insurance companies that prohibit coverage denials because of a pre-existing condition; prohibit the application of annual and lifetime benefits limits on health insurance policies; and prohibit coverage rescissions (except for fraud) and health-based insurance rating. In addition, PPACA, as amended, funds an interim high risk pool that states can draw on; following the expiration of this high risk pool funding, it provides for the creation of state-run “exchanges” that will allow people without employer-provided coverage, or who cannot afford their employer’s plan, to buy health insurance; and provides federal subsidies to those who cannot afford premiums. Collectively, these factors may increase the availability of reimbursement for patients seeking the products that ViroPharma commercializes. However, the Act, as amended, will likely increase certain of our costs as well. For example, an increase in the Medicaid rebate rate from 15.1% to 23.1% was effective as of January 1, 2010, and the volume of rebated drugs has been expanded to include beneficiaries in Medicaid managed care organizations, effective as of March 23, 2010. In 2011, PPACA also imposes a manufacturer’s fee on the sale of branded Pharmaceuticals (excluding orphan drugs) to specified government programs, expands the 340B drug discount program (excluding orphan drugs), and includes a 50% discount on brand name drugs for Medicare Part D participants in the coverage gap, or “doughnut hole”. We have determined that the manufacturing fee is immaterial relative to our anticipated 2011 operating income and cash flow. We have also estimated that our incremental cost associated with the Medicare Part D coverage gap will be approximately \$5.4 million during 2011. Our evaluation of PPACA, as amended, will continue to enable us to determine not only the immediate effects on our business, but also the trends and changes that may be encouraged by the legislation that may potentially impact on our business over time.

We will face intense competition in acquiring additional products to further expand our product portfolio. Many of the companies and institutions that we will compete with in acquiring additional products to further expand our product portfolio have substantially greater capital resources, research and development staffs and facilities than we have, and greater resources to conduct business development activities. We may need additional financing in order to acquire new products in connection with our plans as described in this report. Upon completion of business development transactions, we will face risks related to the integration of the acquired asset or business which could result in delays in development timelines, increased expenses or assumption of undisclosed liabilities, and disruption from the transaction making it more difficult to maintain relationships with manufacturers, employees or other suppliers.

The outcome of our clinical development programs is subject to considerable uncertainties. We are currently undertaking studies on the viability of subcutaneous administration of Cinryze, either alone or in combination with Halozyme’s recombinant human hyaluronidase enzyme (rHuPH20) technology, and to identify further therapeutic uses and potentially expand the labeled indication for Cinryze to include other C1 mediated diseases,

such as AMR and DGF. In addition, we are also developing VP20621 for the treatment and prevention of CDAD and in May 2011 we initiated a Phase 2 dose-ranging clinical study. We anticipate that we will commence pre-clinical and clinical studies with VP-20629 for the treatment of Friedreich's Ataxia. There can be no assurance that that our clinical programs with Cinryze, VP20621 and VP-20629 will yield positive results or support further development. There can be no assurance that the OBS development efforts at Maritage will yield positive results or support further development.

We cannot be certain that we will be successful in developing and ultimately commercializing any of our product candidates, that the FDA or other regulatory authorities will not require additional or unanticipated studies or clinical trial outcomes before granting regulatory approval, or that we will be successful in obtaining regulatory approval of any of our product candidates in the timeframes that we expect, or at all.

We cannot assure you that our current cash and cash equivalents and investments or cash flows from product sales will be sufficient to fund all of our ongoing development and operational costs, as well as the interest payable on our outstanding senior convertible notes, over the next several years, that planned clinical trials can be initiated, or that planned or ongoing clinical trials can be successfully concluded or concluded in accordance with our anticipated schedule and costs. Moreover, the results of our business development efforts could require considerable investments.

Our actual results could differ materially from those results expressed in, or implied by, our expectations and assumption described in this Annual Report on Form 10-K. The risks described in this report, our Form 10-K for the year ended December 31, 2011 are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. Please also see our discussion of the "Risk Factors" in Item 1A, which describe other important matters relating our business.

Results of Operations

Years ended December 31, 2011 and 2010

(in thousands, except per share data)	For the years ended December 31,	
	2011	2010
Net product sales	\$544,374	\$439,012
Cost of sales (excluding amortization of product rights)	\$ 79,976	\$ 61,288
Operating income	\$222,128	\$211,700
Net income	\$140,659	\$125,608
Net income per share:		
Basic	\$ 1.89	\$ 1.61
Diluted	\$ 1.68	\$ 1.47

The \$222.1 million in operating income for the twelve months ended December 31, 2011 increased \$10.4 million compared to the same period in 2010. The primary drivers of this increase are increased net sales of \$105.4 million. Partly offsetting the increased sales are: (1) an increase of \$18.7 million in cost of sales due to increased Cinryze volume; (2) an increase in research and development expense of \$ 26.9 million due to: a \$9.0 million upfront fee and an additional \$3.0 million payment related to the achievement of a development milestone under our license arrangement with Halozyme; a \$6.5 million upfront fee related to our license agreement with Intellect Neurosciences, Inc. (INS); and, (3) an increase of \$32.1 million in selling, general and administrative expenses primarily related to our European expansion efforts and our Cinryze marketing programs. Additionally, we recorded the following in other operating expenses: (1) an impairment charge of approximately \$8.5 million related to certain assets acquired from Auralis; (2) a charge of approximately \$4.6 million related to the changes in the fair value of the Auralis contingent consideration liability; and, (3) a charge

of approximately \$3.4 million of costs associated with the funding of Cinryze manufacturing enhancements at Sanquin.

We sell Diamorphine in the UK, primarily to hospitals, through approved wholesalers. We began commercial sales of Cinryze and Buccolam in Europe during the fourth quarter of 2011. The revenues and operating income from these sales are not material to our consolidated revenues and operating income for 2011 or 2010.

Revenues

Revenues consisted of the following:

(in thousands)	For the years ended December 31,	
	2011	2010
Net product sales		
Vancocin	\$288,893	\$259,567
Cinryze	251,201	176,815
Other	4,280	2,630
Total revenues	<u>\$544,374</u>	<u>\$439,012</u>

Net product sales

Our sales of Vancocin are influenced by wholesaler buying decisions related to their desired inventory levels and patient prescription demand, all of which could be at different levels from period to period.

In the US, we sell Cinryze to specialty pharmacy/specialty distributors (SP/SD's) who then distribute to physicians, hospitals and patients, among others. In Europe, we sell Cinryze to wholesalers who then distribute the product principally to pharmacies and hospitals. We continue to work to expand our manufacturing capacity to ensure the availability of Cinryze to meet growing patient needs and believe our efforts will allow us to continue to meet this growing patient demand for the foreseeable future. In order to meet anticipated longer term demand, we submitted to the FDA a Prior Approval Supplement (PAS) in the second quarter of 2010. The PAS involves a larger scale manufacturing project to significantly increase the Cinryze production capabilities at Sanquin. In October 2010, the FDA issued a complete response letter regarding the Cinryze industrial scale manufacturing expansion activities. In the complete response letter the FDA has requested additional information related to observations from the pre-approval inspection and review of the technical processes. In February 2012, the FDA issued a second complete response letter which included three comments related to a portion of the cleaning validation for industrial scale manufacturing. We believe that only one of the comments requires additional unplanned activity which can be completed in a relatively short time frame. The FDA also noted that it has not yet completed the review of our January 2012 updated responses to observations on Form 483 specific to the September 2011 inspection of the Amsterdam facility. In order to manufacture Cinryze at the industrial scale we must respond to all FDA questions and satisfactorily complete the FDA review, including providing responses to all open observations on Form 483.

During the year ended December 31, 2011, net sales of Vancocin increased 11.3% compared to 2010. The increase is primarily due to net realized price growth period over period. The net increase in Vancocin sales includes the negative impact on sales during 2011 of approximately \$5.4 million in sales deductions related to the Medicare Part D coverage gap discount enacted under PPACA which did not impact net sales in 2010. Based upon data reported by IMS Health Incorporated, prescriptions during the year ended December 31, 2011 decreased from the same period in 2010 by 5.6%, which we believe is due to a decrease in the incidence of severe disease, improved aseptic technique and an increase in compounding, both in the hospital and long-term care marketplace. Our net sales of Cinryze during the year ended December 31, 2011 increased \$74.4 million

compared to the same period in 2010 due to an increase in the number of patients receiving Cinryze. Approximately \$73.4 million of the Cinryze revenue increase was generated in the US.

Vancocin product sales are driven by demand fluctuations in trade inventories which could be at different levels from period to period. Cinryze product sales are influenced by prescriptions and the rate at which new patients are placed on Cinryze, as well as fluctuations in trade and patient inventory levels. We receive inventory data from our three largest wholesalers through our fee for service agreements and our two SP/SD's through service agreements. We do not independently verify this data. Based on this inventory data and our estimates, we believe that as of December 31, 2011, the wholesalers and SP/SD's did not have excess channel inventory of either product.

Cost of sales (excluding amortization of product rights)

Cost of sales increased for the year ended December 31, 2011 by \$18.7 million as compared to the same period in 2010 primarily due to increased Cinryze volume.

Vancocin and Cinryze cost of sales includes the cost of materials and distribution costs and excludes amortization of product rights.

Research and development expenses

For each of our research and development programs, we incur both direct and indirect expenses. Direct expenses include third party costs related to these programs such as contract research, consulting, cost sharing payments or receipts and clinical and development costs. Indirect expenses include personnel, facility, stock compensation and other overhead costs. Due to advancements in our VP20621 clinical program, our Cinryze life cycle management program, the acquisition of DuoCort and the Meritage development agreement, as well as cost associated with our efforts to advance additional initiatives intended to increase our Cinryze capacity and the cost to develop VP-20629 and other compounds, we expect future costs in these programs to increase from historical levels.

Research and development expenses were divided between our research and development programs in the following manner:

(in thousands)	For the years ended December 31,	
	2011	2010
<i>Direct—Core programs</i>		
Non-toxicogenic strains of <i>C. difficile</i> (VP20621)	\$ 7,653	\$ 7,643
Cinryze & C1 esterase inhibitor	23,383	7,113
Vancocin	335	1,151
VP-20629	6,500	—
<i>Direct—Other assets</i>		
CMV	1,028	866
New Initiatives	2,773	2,279
Other assets	478	1,604
<i>Indirect</i>		
Development	24,327	18,957
<i>Total</i>	<u>\$66,477</u>	<u>\$39,613</u>

Direct Expenses—Core Development Programs

The increase in costs of VP20621 for the year ended December 31, 2011 compared to the same period in 2010 relates to timing of costs associated with our Phase 1 clinical trial and the initiation of our Phase 2 clinical trial during the second quarter of 2011.

Our costs associated with our Cinryze program increased during 2011 compared to 2010 as we incurred costs related to the continuation of our Phase 4 clinical trial and development of our life cycle program, including initiation of a Phase 2 study of subcutaneous administration of Cinryze in combination with rHuPH20. In the same period in the prior year, we incurred costs related to the preparation of our Phase 4 clinical trial. During 2011, we made a \$9.0 million upfront payment related to our entering into a license with Halozyme for the development of a subcutaneous formulation of Cinryze for routine prophylaxis against attacks of HAE, and we made a \$3 million payment related to the achievement of a development milestone under our this license arrangement.

Also during 2011, we incurred a \$6.5 million upfront fee related to our license agreement with INS for the clinical stage drug candidate, VP-20629, which is being developed for the treatment of Friedreich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease.

Direct Expenses—Other Assets

Our direct expenses related to our CMV program decreased in 2011 compared to 2010 as we wound down our stem cell and liver transplant studies during 2010. During 2011, we continue to evaluate potential alternative development strategies for maribavir.

Our costs related to New Initiatives represent expenses associated with our evaluation of a recombinant C1-INH technology and spending under our collaboration agreement with Sanquin supporting their Early Stage Research Programs.

Anticipated fluctuations in future direct expenses are discussed under “**Liquidity—Development Programs.**”

Indirect Expenses

These costs primarily relate to the compensation of and overhead attributable to our development team.

Selling, general and administrative expenses (SG&A)

In 2011 compared to 2010, SG&A increased \$32.1 million. This increase was primarily driven by higher compensation expense and employee cost of \$14.5 million, increased marketing expenses of \$9.4 million and increased corporate cost of \$3.6 million.

Our European infrastructure and commercialization efforts and new Cinryze marketing programs in the US are predominant reasons for the overall increase in SG&A in both periods. We anticipate that our SG&A spending will continue to increase in future periods as we continue our commercialization and expansion efforts outside the United States.

Intangible amortization and acquisition of technology rights

Intangible amortization for the year ended December 31, 2011 was \$31.0 million, as compared to \$29.4 million in 2010. The year over year increases are primarily due to the amortization of the Auralis intangible assets acquired in May of 2010.

Impairment losses

Due to the approval and launch of Buccolam, coupled with the launch of Cinryze in Europe, we have decided to alter our development and commercialization plans for the remaining Auralis IPR&D asset. The decision resulted in the impairment of the IPR&D asset and the Auralis Contract rights. Accordingly, we recorded a charge of approximately £5.4 million (approximately \$8.5 million) during 2011.

Other operating expenses

The re-measurement of the fair value of the contingent consideration given for the acquisition of Auralis resulted in a charge to income of approximately \$4.6 million during 2011. We incurred expense of approximately \$1.4 million for the re-measurement of the fair value of the contingent consideration during 2010. Also included in other operating expenses for 2011 is approximately \$3.4 million of costs associated with the funding of Cinryze manufacturing enhancements at Sanquin.

Other Income (Expense)

Interest Income

Interest income for year ended December 31, 2011 was \$0.7 million and \$0.4 million in 2010.

Interest Expense

(in thousands)	For the years ended December 31,	
	2011	2010
Interest expense	\$ 4,372	\$ 4,100
Amortization of debt discount	7,711	7,129
Amortization of finance costs	557	387
Total interest expense	<u>\$12,640</u>	<u>\$11,616</u>

Interest expense and amortization of debt discount and finance costs in 2011 and 2010 relates primarily to the senior convertible notes issued on March 26, 2007. Also include in the 2011 amounts is the amortization of the debt issue cost associated with the \$200 million credit facility entered into during the third quarter of 2011 as well as commitment fees on the unused facility.

Other income, net

Our other income, net includes net foreign exchange gains and losses.

Income Tax Expense

Our income tax expense was \$67.3 million and \$75.3 million for 2011 and 2010, respectively. Our income tax expense includes federal, state and foreign income taxes at statutory rates and the effects of various permanent differences.

Our effective tax rates for 2011 and 2010 were 32.4% and 37.5%, respectively. Our effective tax rate in 2011 is lower than the statutory U.S. tax rate due to domestic manufacturing tax deductions and a reduction in the valuation allowance for state net operating losses partly offset by state income taxes, and by certain share-based compensation and an increase in the fair value of contingent consideration, neither of which is deductible for tax purposes. Our effective tax rate in 2010 was higher than the statutory U.S. tax rate primarily due to state income taxes and certain share-based compensation that is not tax deductible.

The examination of our 2008 U.S. income tax return concluded during the quarter ended March 31, 2011 with no material adjustments. We are currently under examination in a foreign jurisdiction and by various states. At this time, we do not believe that the results of these examinations will have a material impact on our financial statements.

Results of Operations

Years ended December 31, 2010 and 2009

(in thousands, except per share data)	For the years ended December 31,	
	2010	2009
Net product sales	\$439,012	\$310,449
Cost of sales (excluding amortization of product rights)	\$ 61,288	\$ 40,214
Operating income	\$211,700	\$ 32,130
Net (loss) income	\$125,608	\$ (11,077)
Net (loss) income per share:		
Basic	\$ 1.61	\$ (0.14)
Diluted	\$ 1.47	\$ (0.14)

The \$211.7 million in operating income for the twelve months ended December 31, 2010 increased \$179.6 million as compared to the same period in 2009. The primary drivers of this increase are increased net sales of \$128.6 million, the \$65.1 million goodwill impairment charge in the first quarter of 2009 for which no impairment occurred in 2010, and, a decrease in our research and development expense of \$12.5 million primarily due to the wind-down of our CMV program. These were partly offset from increased cost of sales \$21.1 million due to the increase in Cinryze sales volume and a \$6.3 million increase in selling, general and administrative expense.

Revenues

Revenues consisted of the following:

(in thousands)	For the years ended December 31,	
	2010	2009
Net product sales		
Vancocin	\$259,567	213,138
Cinryze	176,815	97,311
Other	2,630	—
Total Revenues	<u>\$439,012</u>	<u>\$310,449</u>

Revenue—Vancocin and Cinryze product sales

During the year ended December 31, 2010, net sales of Vancocin increased 21.8% compared to 2009. The increase is primarily due to price increases during 2010, offset by lower sales volumes. Based upon data reported by IMS Health Incorporated, prescriptions during the year ended December 31, 2010 decreased from the same period in 2009 by 5.8%, which we believe is due to a decrease in the severity of the disease state, improved aseptic techniques and a suspected increase in compounding seen both in the hospital and long-term care marketplace. The units sold for the year ended December 31, 2010 decreased by 1.4% compared to the same period in 2009. Our net sales of Cinryze during the year ended December 31, 2010 increased \$79.5 million compared to the same period in 2009 due to an increase in the number of patients receiving Cinryze.

Vancocin product sales are driven by demand fluctuations in trade inventories which could be at different levels from period to period. Cinryze product sales are influenced by prescriptions and the rate at which new patients are placed on Cinryze. We receive inventory data from our three largest wholesalers through our fee for service agreements and our two SP/SD's through service agreements. We do not independently verify this data. Based on this inventory data and our estimates, we believe that as of December 31, 2010, the wholesalers and SP/SD's did not have excess channel inventory of either product.

Cost of sales (excluding amortization of product rights)

Cost of sales increased for the year ended December 31, 2010 by \$21.1 million as compared to the same period in 2009 due to increased Cinryze volume, partially offset by the impact of the step-up on 2009 cost of sales related to the acquisition of Lev (\$6.9 million). We utilized the entire inventory that was recorded at fair value as part of the Lev purchase during 2009. Additionally, included in the cost of sales for the year ended December 31, 2010 are expenses of \$1.5 million related to non-refundable start up costs paid to a new plasma supplier and a \$2.8 million write-off of inventory, produced as part of our effort to receive FDA approval for a larger scale manufacturing line.

Vancocin and Cinryze cost of sales includes the cost of materials and distribution costs and excludes amortization of product rights. Since units are shipped based upon earliest expiration date, we would expect the cost of product sales of both Vancocin and Cinryze to fluctuate from quarter to quarter as we may experience fluctuations in quarterly manufacturing yields.

Research and development expenses

For each of our research and development programs, we incur both direct and indirect expenses. Direct expenses include third party costs related to these programs such as contract research, consulting, cost sharing payments or receipts and clinical and development costs. Indirect expenses include personnel, facility, stock compensation and other overhead costs. Due to advancements in our VP20621 preclinical program, and our Cinryze Phase 4 commitment and Phase 2 study in children, we expect future costs in these programs to exceed historical costs.

Research and development expenses were divided between our research and development programs in the following manner:

(in thousands)	For the years ended December 31,	
	2010	2009
Direct—Core programs		
Non-toxicogenic strains of <i>C. difficile</i> (VP20621)	\$ 7,643	\$ 9,801
Cinryze	7,113	7,067
Vancocin	1,151	675
Direct—Other assets		
CMV	866	15,715
New Initiatives	2,279	—
Other assest	1,604	8
Indirect		
Development	18,957	18,817
Total	\$39,613	\$52,083

Direct Expenses—Core Development Programs

The decrease in costs of VP20621 for the year ended December 31, 2010 compared to the same period in 2009 relates to timing associated with costs of our Phase 1 clinical trial.

Our costs associated with our Cinryze program during 2010 are flat compared to 2009, as we incurred costs related to our Phase 4 clinical trial and the development of our life cycle program during 2010, while during 2009, we incurred costs related to our open label trials which closed on March 31, 2009 and preparation of our Phase 4 clinical trial.

Vancocin costs in 2010 and 2009 related to additional research activities.

Direct Expenses—Other Assets

Our direct expenses related to our CMV program decreased in 2010 compared to 2009 as we wound down our stem cell and liver transplant studies in 2009. In February 2009, based upon preliminary analysis of the data, we announced that our Phase 3 trial evaluating maribavir used as prophylaxis in allogeneic stem cell, or bone marrow, transplant patients did not achieve its primary endpoints. In addition, the study failed to meet its key secondary endpoints. Additionally, we announced that our Phase 3 trial evaluating maribavir in liver transplant patients was discontinued and that all patients on study drug were moved to current standard of care. During 2009 we continued enrollment in our solid organ (liver) study through February 2009, conducted follow-up visits necessary to complete both our Phase 3 studies following receipt of the results of our stem cell transplant study and continued to evaluate the results of our Phase 3 programs. We continue to evaluate any potential alternative development strategies for maribavir.

Our costs related to New Initiatives represent expenses associated with our evaluation of a recombinant C1-INH technology and spending under our collaboration agreement with Sanquin supporting their Early Stage Research Programs. Included in the 2010 Other assets is a one-time charge of approximately \$1.1 million associated with a re-negotiation of a royalty arrangement on a product in late stage development.

Anticipated fluctuations in future direct expenses are discussed under “**Liquidity—Development Programs.**”

Indirect Expenses

These costs primarily relate to the compensation of and overhead attributable to our development team. During the second half of 2009 and through 2010, our development team shifted its focus from our CMV program to our Cinryze and VP20621 programs.

Selling, general and administrative expenses

Selling, general and administrative expenses (SG&A) increased \$6.3 million during 2010 compared to 2009. The increase was driven by increased marketing expenses (\$2.9 million), legal costs (\$2.2 million), compensation expense (\$1.7 million) and increased costs associated with our activities in Europe, partly offset by decreased medical education expenses (\$2.6 million).

Included in SG&A are legal and consulting costs incurred related to our opposition to the attempt by the OGD regarding the conditions that must be met in order for a generic drug application to request a waiver of in-vivo bioequivalence testing for copies of Vancocin, which were \$6.4 million and \$5.5 million for the years 2010 and 2009, respectively. We anticipate that these additional legal and consulting costs will continue at the current level, or possibly higher, in future periods as we continue this opposition. We anticipate continued increased spending in selling, general and administrative expenses in future periods as we continue to implement additional commercial programs related to Cinryze and continue our European initiatives.

Intangible amortization and acquisition of technology rights

Intangible amortization for the year ended December 31, 2010 was \$29.4 million, as compared to \$28.2 million in 2009.

On an ongoing periodic basis, we evaluate the useful life of our intangible assets and determine if any economic, governmental or regulatory event has modified their estimated useful lives. This evaluation did not result in a change in the life of the intangible assets during the year ended December 31, 2010. We will continue to monitor the actions of the FDA and OGD surrounding the bioequivalence recommendation for Vancocin and consider the

effects of our opposition efforts, any announcements by generic competitors or other adverse events for additional impairment indicators. We will reevaluate the expected cash flows and fair value of our Vancocin-related assets, as well as estimated useful lives, at such time.

Impairment losses

During the first quarter of 2009, the market capitalization of ViroPharma fell below the carrying value of ViroPharma's net assets due to the announcements surrounding our maribavir development program. This situation required us to test for impairment of our goodwill and other intangible assets which lead to a goodwill impairment charge of \$65.1 million in 2009. There was no impairment of goodwill during 2010.

During 2009 we incurred an impairment charge related to our previous corporate headquarters of \$3.4 million due to the down turn in the real estate market.

Other operating expenses

The re-measurement of the fair value of the contingent consideration given relating to the acquisition of Auralis resulted in a charge to income during the period ended December 31, 2010 of \$1.4 million. There was no such charge during 2009.

Other Income (Expense)

Interest Income

Interest income for year ended December 31, 2010 was \$0.4 million is flat compared to \$0.4 million in 2009.

Interest Expense

(in thousands)	For the years ended December 31,	
	2010	2009
Interest expense on senior convertible notes	\$ 4,100	\$ 4,343
Amortization of debt discount	7,129	6,854
Amortization of finance costs	387	412
Total interest expense	<u>\$11,616</u>	<u>\$11,609</u>

Interest expense and amortization of debt discount and finance costs in 2010 and 2009 relates entirely to the senior convertible notes issued on March 26, 2007.

Other income, net

Our other income, net includes net foreign exchange gains and the rental income attributable to our previous corporate headquarters.

Income Tax Expense

Our income tax expense was \$75.3 million and \$41.0 million for the year ended December 31, 2010 and 2009, respectively. The effective tax rate in 2010 was 37.5% compared to 137.0% in 2009. The effective tax rate in 2010 exceeded the federal statutory tax rate due to state income taxes and certain share-based compensation that is not tax deductible. The effective tax rate in 2009 exceeded the statutory tax rate because of a goodwill impairment charge which is not deductible for tax purposes and state income taxes, partially offset by an orphan drug credit.

Liquidity

In the near term, we expect that our sources of revenue will continue to arise from Cinryze and Vancocin product sales. We began the commercial sales of Buccolam and Cinryze in Europe during the fourth quarter of 2011. However, future sales of Vancocin will vary based on the number of generic competitors that could enter the market if the three-year exclusivity period is not granted by the FDA as a result of the FDA's approval of a supplemental new drug application (sNDA) for Vancocin (or if FDA decides that any protected labeling can be omitted from the labels of generic products), and if generics are permitted to demonstrate bioequivalence through an in vitro dissolution method, the timing of entry into the market of those generic competitors and/or the sales we may generate from an authorized generic version of Vancocin. In addition, there are no assurances that demand for Cinryze will continue to grow or that demand for Vancocin will continue at historical or current levels.

Although we began commercial sales of Cinryze and Buccolam in Europe during the fourth quarter of 2011, the revenues and operating income from these sales are not material to our consolidated revenues and operating income for 2011 and there are no assurances that there will be growing demand for products in Europe or we will be successful in our commercialization efforts in Europe or any other territories we have the rights to sell these drug products.

Our ability to generate positive cash flow is also impacted by the timing of anticipated events in our Cinryze, VP20621, VP-20629, Plenadren and other development programs, including the timing of our expansions into other territories and the costs of our anticipated commercial activities, the scope of the clinical trials required by regulatory authorities, results from clinical trials, the results of our product development efforts, including the OBS development efforts at Meritage and variations from our estimate of future direct and indirect expenses.

The cash flows we have used in operations historically have been applied to research and development activities, marketing and commercial efforts, business development activities, general and administrative expenses, debt service, and income tax payments. Bringing drugs from the preclinical research and development stage through phase 1, phase 2, and phase 3 clinical trials and FDA and/or EMA or regulatory approval is a time consuming and expensive process. Because we have product candidates that are currently in the clinical stage of development, there are a variety of events that could occur during the development process that will dictate the course we must take with our drug development efforts and the cost of these efforts. As a result, we cannot reasonably estimate the costs that we will incur through the commercialization of any product candidate. However, our future costs may exceed current costs as we anticipate we will continue to invest in our pipeline, including our initiative to develop VP20621 (non-toxicogenic strains of *C. difficile*), VP-20629, any additional studies to identify further therapeutic uses and expand the labeled indication for Cinryze to potentially include other C1 mediated diseases as well as new modes of administration for Cinryze. Also, we will incur additional costs as we intend to seek to commercialize Cinryze, Buccolam and Plenadren in Europe in countries where we have distribution rights and certain other countries beginning in 2011 as well as conduct studies to identify additional C1 mediated diseases, such as AMR and DGF, which may be of interest for further clinical development, and to evaluate new forms of administration for Cinryze.

In May 2011, Halozyme Therapeutics (Halozyme) granted us an exclusive worldwide license to use Halozyme's proprietary Enhance™ technology, a proprietary drug delivery platform using Halozyme's recombinant human hyaluronidase enzyme (rHuPH20) technology in combination with a C1 esterase inhibitor. We intend to apply rHuPH20 initially to develop a novel subcutaneous formulation of Cinryze for routine prophylaxis against attacks. Under the terms of the license agreement, we paid Halozyme an initial upfront payment of \$9 million. In the fourth quarter of 2011, we made a milestone payment of \$3 million related to the initiation of a Phase 2 study begun in September 2011 to evaluate the safety, and pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20. Pending successful completion of an additional series of clinical and regulatory milestones, anticipated to begin during 2012, we may make further milestone payments to Halozyme which could reach up to an additional \$41 million related to HAE and up to \$30 million of

additional milestone payments for three additional indications. Additionally, we will pay an annual maintenance fee of \$1 million to Halozyme until specified events have occurred. Upon regulatory approval, Halozyme will receive up to a 10% royalty on net sales of the combination product utilizing Cinryze and rHuPH20, depending on the existence of a valid patent claim in the country of sale.

On September 30, 2011, we entered into a license agreement for the worldwide rights of Intellect Neurosciences, Inc. (INS) to its clinical stage drug candidate, VP-20629, being developed for the treatment of Friedreich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease. We expect to initiate a phase 2 study within 12 to 18 months of the date of this agreement, after completion of longer-term toxicology studies. We intend to file for Orphan Drug Designation upon review of the phase 2 proof of concept data. Under the terms of the agreement, we have exclusive worldwide rights to develop and commercialize VP-20629 for the treatment, management or prevention of any disease or condition covered by Intellect's patents. We paid INS a \$6.5 million up-front licensing fee and may pay additional milestones up to \$120 million based upon defined events. We will also pay a tiered royalty of up to a maximum percentage of low teens, based on annual net sales.

On October 21, 2008, we completed our acquisition under which ViroPharma acquired Lev Pharmaceuticals, Inc. (Lev). Lev is a biopharmaceutical company focused on developing and commercializing therapeutic products for the treatment of inflammatory diseases. The terms of the merger agreement provided for the conversion of each share of Lev common stock into upfront consideration of \$453.1 million, or \$2.75 per Lev share, comprised of \$2.25 per share in cash and \$0.50 per share in ViroPharma common stock, and contingent consideration of up to \$1.00 per share which may be paid on achievement of certain regulatory and commercial milestones. The target for the first CVR payment of \$0.50 per share (or \$87.5 million) will not be paid as a third party's human C1 inhibitor product was approved for the acute treatment of HAE and granted orphan exclusivity. The second CVR payment of \$0.50 per share (\$87.5 million) becomes payable if Cinryze reaches at least \$600 million in cumulative net product sales by October 2018. As of December 31, 2011, we have recognized approximately \$525.3 million of cumulative sales of Cinryze and we anticipate achieving this milestone in 2012.

On November 15, 2011, we acquired a 100% ownership interest in DuoCort Pharma AB (DuoCort), a private company based in Helsingborg, Sweden focused on improving glucocorticoid replacement therapy for treatment of adrenal insufficiency, or Addison's disease (AD). We paid approximately 213 million Swedish Krona (SEK) or approximately \$32.1 million in upfront consideration. We have also agreed to make additional payments ranging from SEK 240 million up to SEK 860 million or approximately \$35 million to \$124 million, contingent on the achievement of certain milestones. Up to SEK 160 million or approximately \$23 million of the contingent payments relate to specific regulatory milestones; and up to SEK 700 million or approximately \$101 million of the contingent payments are related to commercial milestones based on the success of the product.

On December 22, 2011, we entered into an exclusive development and option agreement with Meritage Pharma, Inc. (Meritage), a private company based in San Diego, CA focused on developing oral budesonide suspension (OBS) as a treatment for eosinophilic esophagitis (EoE). As consideration for the agreement, we paid an initial \$7.5 million and have the option to provide Meritage up to an additional \$12.5 million for the development of OBS. Meritage will utilize the funding to conduct additional Phase 2 clinical assessment of OBS. We have an exclusive option to acquire Meritage, at our sole discretion, by providing written notice at any time during the period from December 22, 2011 to and including the date that is the earlier of (a) the date that is 30 business days after the later of (i) the receipt of the final study data for the Phase 2 study and (ii) identification of an acceptable clinical end point definition for a pivotal induction study agreed to by the FDA. If we exercise this option, we have agreed to pay \$69.9 million for all of the outstanding capital stock of Meritage. Meritage stockholders could also receive additional payments of up to \$175 million, upon the achievement of certain clinical and regulatory milestones.

The most significant of our near-term operating development cash outflows are as described under "**Development Programs**" as set forth below.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA). The PPACA, as amended, will likely increase certain of our costs as well. For example, an increase in the Medicaid rebate rate from 15.1% to 23.1% was effective as of January 1, 2010, and the volume of rebated drugs has been expanded to include beneficiaries in Medicaid managed care organizations, effective as of March 23, 2010. Beginning in 2011, the PPACA also imposes a manufacturer's fee on the sale of branded Pharmaceuticals (excluding orphan drugs) to specified government programs, expands the 340B drug discount program (excluding orphan drugs), and includes a 50% discount on brand name drugs for Medicare Part D participants in the coverage gap, or "donut hole". We have determined that the manufacturing fee is immaterial relative to our anticipated 2011 operating income and cash flow. We have also estimated that our incremental cost associated with the Medicare Part D coverage gap will be approximately \$5.4 million during 2011. Our evaluation of PPACA, as amended, will continue to enable us to determine not only the immediate effects on our business, but also the trends and changes that may be encouraged by the legislation that may potentially impact on our business over time.

Capital Resources

While we anticipate that cash flows from Cinryze and Vancocin, our current cash, cash equivalents and short-term investments (together, "our cash") and revolving credit facility should allow us to fund our ongoing development and operating costs, as well our interest payments and future milestone payments or acquisition costs, we may need additional financing in order to expand our product portfolio. At December 31, 2011, we had cash, cash equivalents and short-term investments of \$459.8 million. Short-term investments consist of high quality fixed income securities with remaining maturities of greater than three months at the date of purchase and high quality debt securities or obligation of departments or agencies of the United States. At December 31, 2011, the annualized weighted average nominal interest rate on our short-term investments was 0.38% and the weighted average length to maturity was 7.0 months. At December 31, 2011, we also had \$200 million available under our revolving credit agreement. At December 31, 2011, approximately \$194.5 million of our cash and availability under the credit agreement is subject to the minimum liquidity covenant, as defined in our credit agreement.

Financing

Should we need financing, we would seek to access the public or private equity or debt markets, enter into additional arrangements with corporate collaborators to whom we may issue equity or debt securities or enter into other alternative financing arrangements that may become available to us.

If we raise additional capital by issuing equity securities, the terms and prices for these financings may be much more favorable to the new investors than the terms obtained by our existing stockholders. These financings also may significantly dilute the ownership of existing stockholders.

If we raise additional capital by accessing debt markets, the terms and pricing for these financings may be much more favorable to the new lenders than the terms obtained from our prior lenders. These financings also may require liens on certain of our assets that may limit our flexibility.

Additional equity or debt financing, however, may not be available on acceptable terms from any source as a result of, among other factors, our operating results, our inability to achieve regulatory approval of any of our product candidates, and our inability to file, prosecute, defend and enforce patent claims and or other intellectual property rights. If sufficient additional financing is not available, we may need to delay, reduce or eliminate current development programs, or reduce or eliminate other aspects of our business.

From time to time, we may seek approval from our board of directors to evaluate additional opportunities to repurchase our common stock or convertible notes, including through open market purchases or individually negotiated transactions.

Overall Cash Flows

During the twelve months ended December 31, 2011, we generated \$170.7 million of net cash from operating activities, primarily from our net income after adjustments for non-cash items, including the charge for the intangible assets impairment, partly offset by our net increase in working capital and our payment of the Auralis contingent consideration. The decrease from 2010 is primarily related to higher cash payments for taxes during 2011. We used \$101.0 million of cash from investing activities mainly in the purchase of short-term investments, net of investment maturities and the acquisition of DuoCort. Our net cash used in financing activities for the twelve months ended December 31, 2011 was \$163.2 million is primarily attributable to the repurchases of our common stock and our payment of the Auralis contingent consideration. During the year ended December 31, 2010, we generated \$193.5 million of net cash from operating activities, primarily from our net income after adjustments for non-cash items. We used \$101.9 million of cash from investing activities mainly in the purchase of short-term investments, as well as in the purchase of Auralis and the additional purchase price consideration for Vancocin. Our net cash provided by financing activities was \$3.6 million which relates to stock option exercises.

Development Programs

For each of our development programs, we incur both direct and indirect expenses. Direct expenses include third party costs related to these programs such as contract research, consulting, cost sharing payments or receipts, and preclinical and clinical development costs. Indirect expenses include personnel, facility and other overhead costs. Additionally, for some of our development programs, we have cash inflows and outflows upon achieving certain milestones.

Core Development Programs

Cinryze—We acquired Cinryze in October 2008 and through December 31, 2011 have spent approximately \$42.8 million in direct research and development costs related to Cinryze since acquisition. During 2012, we continue to expect research and development costs related to Cinryze to increase as we complete our Phase 4 commitment and initiate our Phase 2 study to evaluate Cinryze for treatment of acute HAE in children. Additionally, we will incur costs related to evaluating additional indications, formulations and territories as we develop our life cycle program related to Cinryze such as our efforts on the C1 esterase inhibitor/rHuPH20 combination sub-subcutaneous formulation, AMR and DGF. We are solely responsible for the costs of Cinryze development. In September 2011, we initiated a Phase 2 study to evaluate the safety, and pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20.

VP20621—We acquired VP20621 in February 2006 and through December 31, 2011 have spent approximately \$31.5 million in direct research and development costs. For the remainder of 2011, we expect our research and development activities related to VP20621 to increase as we continue our development program and in May 2011, we initiated a Phase 2 dose-ranging clinical study to evaluate the safety, tolerability, and efficacy of VP 20621 for prevention of recurrence of CDAD in adults previously treated for CDAD. We are solely responsible for the costs of VP20621 development.

Vancocin—We acquired Vancocin in November 2004 and through December 31, 2011 have spent approximately \$3.1 million in direct research and development costs related to Vancocin activities since acquisition.

VP-20629—On September 30, 2011, we entered into a license agreement for the worldwide rights of Intellect Neurosciences, Inc. (INS) to its clinical stage drug candidate, VP-20629, being developed for the treatment of Friedreich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease. We expect to initiate a phase 2 study within 12 to 18 months of the date of this agreement, after completion of longer-term toxicology studies. We intend to file for Orphan Drug Designation upon review of the phase 2 proof of concept data. Under the terms of the agreement, we have exclusive worldwide rights to develop and commercialize VP-20629 for the treatment, management or prevention of any disease or condition covered by Intellect's patents. We paid INS a

\$6.5 million up-front licensing fee and may pay additional milestones up to \$120 million based upon defined events. We will also pay a tiered royalty of up to a maximum percentage of low teens, based on annual net sales. We are solely responsible for the costs of VP-20629 development.

Other Assets

In addition to the programs described above, we have several other assets that we may make additional investments in. These investments will be dependent on our assessment of the potential future commercial success of or benefits from the asset. These assets include maribavir for CMV, and other compounds. We will continue to incur costs associated with our other development assets for direct research and development costs for medicinal products which will address unmet medical needs such as our current evaluation of a recombinant C1-INH technology which may be included in future clinical studies.

Business Development Activities

On December 22, 2011, we entered into an exclusive development and option agreement with Meritage Pharma, Inc. (Meritage), a private company based in San Diego, CA focused on developing oral budesonide suspension (OBS) as a treatment for eosinophilic esophagitis (EoE). We have an exclusive option to acquire Meritage, at our sole discretion, by providing written notice at any time during the period from December 22, 2011 to and including the date that is the earlier of (a) the date that is 30 business days after the later of (i) the receipt of the final study data for the Phase 2 study and (ii) identification of an acceptable clinical end point definition for a pivotal induction study agreed to by the FDA. As consideration for the option, we paid an initial \$7.5 million and have the option to provide Meritage up to an additional \$12.5 million for the development of OBS. Meritage will utilize the funding to conduct additional Phase 2 clinical assessment of OBS. If we exercise this option, we have agreed to pay \$69.9 million for all of the outstanding capital stock of Meritage. Meritage stockholders could also receive additional payments of up to \$175 million, upon the achievement of certain clinical and regulatory milestones.

On November 15, 2011, we acquired a 100% ownership interest in DuoCort Pharma AB (DuoCort), a private company based in Helsingborg, Sweden focused on improving glucocorticoid replacement therapy for treatment of adrenal insufficiency, or Addison's disease (AD). We paid approximately 213 million Swedish Krona (SEK) or approximately \$32.1 million in upfront consideration. We have also agreed to make additional payments ranging from SEK 240 million up to SEK 860 million or approximately \$35 million to \$124 million, contingent on the achievement of certain milestones. Up to SEK 160 million or approximately \$23 million of the contingent payments relate to specific regulatory milestones; and up to SEK 700 million or approximately \$101 million of the contingent payments are related to commercial milestones based on the success of the product.

On September 30, 2011, we entered into a license agreement for the worldwide rights of Intellect Neurosciences, Inc. (INS) to its clinical stage drug candidate, VP-20629, being developed for the treatment of Friedreich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease. We paid INS a \$6.5 million up-front licensing fee and may pay additional milestones up to \$120 million based upon defined events. We will also pay a tiered royalty of up to a maximum percentage of low teens, based on annual net sales. We are solely responsible for the costs of VP-20629 development.

On May 28, 2010, we acquired a 100% ownership interest in Auralis Limited, a UK based specialty pharmaceutical company for approximately \$14.5 million in upfront consideration for the acquisition of the company and its existing pharmaceutical licenses and products. During the third quarter of 2011, we made additional payment of £10 million Pounds Sterling (approximately \$15.8 million) upon the European Commission grant of a Centralized Pediatric Use Marketing Authorization (PUMA) for Buccolam during the quarter.

We intend to continue to seek to acquire additional products or product candidates. The costs associated with evaluating or acquiring any additional product or product candidate can vary substantially based upon market

size of the product, the commercial effort required for the product, the product's current stage of development, and actual and potential generic and non-generic competition for the product, among other factors. Due to the variability of the cost of evaluating or acquiring business development candidates, it is not feasible to predict what our actual evaluation or acquisition costs would be, if any, however, the costs could be substantial.

Share Repurchase Program

On March 9, 2011 our Board of Directors authorized the use of up to \$150.0 million to repurchase shares of our common stock and/or our 2% Senior Convertible Notes due 2017. Purchases may be made by means of open market transactions, block transactions, privately negotiated purchase transactions or other techniques from time to time. The sources of cash for this repurchase program were a combination of our available liquid assets and/or our cash flows from operations.

On March 14, 2011, we entered into a three month accelerated share repurchase (ASR) agreement with a large financial institution to repurchase \$50.0 million of our common stock on an accelerated basis. We paid \$50.0 million to the financial institution and received approximately 2.7 million shares under this arrangement at an average purchase price of \$18.74 per share.

During the third quarter of 2011, we reacquired approximately 5.5 million shares of our common stock at a cost of approximately \$98.9 million or an average price of \$18.04 per share. These purchases effectively completed our repurchase program authorized by our board on March 9, 2011.

On September 14, 2011, our Board of Directors authorized the use of up to an additional \$200 million to repurchase shares of our common stock and/or our 2% Senior Convertible Notes due 2017. Purchases may be made by means of open market transactions, block transactions, privately negotiated purchase transactions or other techniques from time to time. To the extent repurchases are made, the sources of cash for this program are expected to be a combination of our available liquid assets and/or cash flows from operations.

During the fourth quarter of 2011, we reacquired approximately 1.0 million shares through open market transactions at a cost of approximately \$20.8 million or an average price of \$20.62 per share.

From time to time, we may seek approval from our board of directors to evaluate additional opportunities to repurchase our common stock or convertible notes, including through open market purchases or individually negotiated transactions.

Senior Convertible Notes

On March 26, 2007, we issued \$250.0 million of 2% senior convertible notes due March 2017 (the "senior convertible notes") in a public offering. Net proceeds from the issuance of the senior convertible notes were \$241.8 million. The senior convertible notes are unsecured unsubordinated obligations and rank equally with any other unsecured and unsubordinated indebtedness. The senior convertible notes bear interest at a rate of 2% per annum, payable semi-annually in arrears on March 15 and September 15 of each year commencing on September 15, 2007.

The debt and equity components of our senior convertible debt securities are bifurcated and accounted for separately based on the value and related interest rate of a non-convertible debt security with the same terms. The fair value of a non-convertible debt instrument at the original issuance date was determined to be \$148.1 million. The equity (conversion options) component of our convertible debt securities is included in Additional paid-in capital on our Consolidated Balance Sheet and, accordingly, the initial carrying value of the debt securities was reduced by \$101.9 million. Our net income for financial reporting purposes is reduced by recognizing the accretion of the reduced carrying values of our convertible debt securities to their face amount of \$250.0 million as additional non-cash interest expense. Accordingly, the senior convertible debt securities will recognize interest expense at effective rates of 8.0% as they are accreted to par value.

As of December 31, 2011 senior convertible notes representing \$205.0 million of principal debt are outstanding with a carrying value of \$153.5 million and a fair value of approximately \$318.6 million, based on the level 2 valuation hierarchy of the fair value measurements standard.

The senior convertible notes are convertible into shares of our common stock at an initial conversion price of \$18.87 per share. The senior convertible notes may only be converted: (i) anytime after December 15, 2016; (ii) during the five business-day period after any five consecutive trading day period (the “measurement period”) in which the price per note for each trading day of that measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such day; (iii) during any calendar quarter (and only during such quarter) after the calendar quarter ending June 30, 2007, if the last reported sale price of our common stock for 20 or more trading days in a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter exceeds 130% of the applicable conversion price in effect on the last trading day of the immediately preceding calendar quarter; or (iv) upon the occurrence of specified corporate events. Upon conversion, holders of the senior convertible notes will receive shares of common stock, subject to ViroPharma’s option to irrevocably elect to settle all future conversions in cash up to the principal amount of the senior convertible notes, and shares for any excess. We can irrevocably elect this option at any time on or prior to the 35th scheduled trading day prior to the maturity date of the senior convertible notes. The senior convertible notes may be required to be repaid on the occurrence of certain fundamental changes, as defined in the senior convertible notes.

Concurrent with the issuance of the senior convertible notes, we entered into privately-negotiated transactions, comprised of purchased call options and warrants sold, to reduce the potential dilution of our common stock upon conversion of the senior convertible notes. The transactions, taken together, have the effect of increasing the initial conversion price to \$24.92 per share. The net cost of the transactions was \$23.3 million.

The call options allowed ViroPharma to receive up to approximately 13.25 million shares of its common stock at \$18.87 per share from the call option holders, equal to the number of shares of common stock that ViroPharma would issue to the holders of the senior convertible notes upon conversion. These call options will terminate upon the earlier of the maturity dates of the related senior convertible notes or the first day all of the related senior convertible notes are no longer outstanding due to conversion or otherwise. Concurrently, we sold warrants to the warrant holders to receive shares of its common stock at an exercise price of \$24.92 per share. These warrants expire ratably over a 60-day trading period beginning on June 13, 2017 and will be net-share settled.

The purchased call options are expected to reduce the potential dilution upon conversion of the senior convertible notes in the event that the market value per share of ViroPharma common stock at the time of exercise is greater than \$18.87, which corresponds to the initial conversion price of the senior convertible notes, but less than \$24.92 (the warrant exercise price). The warrant exercise price is 75.0% higher than the price per share of \$14.24 of our common stock on the pricing date. If the market price per share of ViroPharma common stock at the time of conversion of any senior convertible notes is above the strike price of the purchased call options (\$18.87), the purchased call options will entitle us to receive from the counterparties in the aggregate the same number of shares of our common stock as we would be required to issue to the holder of the converted senior convertible notes. Additionally, if the market price of ViroPharma common stock at the time of exercise of the sold warrants exceeds the strike price of the sold warrants (\$24.92), we will owe the counterparties an aggregate of approximately 13.25 million shares of ViroPharma common stock. If we have insufficient shares of common stock available for settlement of the warrants, we may issue shares of a newly created series of preferred stock in lieu of our obligation to deliver common stock. Any such preferred stock would be convertible into 10% more shares of our common stock than the amount of common stock we would otherwise have been obligated to deliver under the warrants.

Initially, the purchased call options and warrants sold with the terms described above were based upon the \$250.0 million offering, and the number of shares we would purchase under the call option and the number of shares we would sell under the warrants was 13.25, to correlate to the \$250.0 million principal amount. On March 24, 2009

we repurchased, in a privately negotiated transaction, \$45.0 million in principal amount of our senior convertible notes due March 2017 for total consideration of approximately \$21.2 million. The repurchase represented 18% of our then outstanding debt and was executed at a price equal to 47% of par value. Additionally, in negotiated transactions, we sold approximately 2.38 million call options for approximately \$1.8 million and repurchased approximately 2.38 million warrants for approximately \$1.5 million which terminated the call options and warrants that were previously entered into by us in March 2007. We recognized a \$9.1 million gain in the first quarter of 2009 as a result of this debt extinguishment. For tax purposes, the gain qualifies for deferral until 2014 in accordance with the provisions of the American Recovery and Reinvestment Act.

As a result of the above negotiated sale and purchase transactions we are now entitled to receive approximately 10.87 million shares of our common stock at \$18.87 from the call option holders and if the market price of ViroPharma common stock at the time of exercise of the sold warrants exceeds the strike price of the sold warrants (\$24.92), will owe the counterparties an aggregate of approximately 10.87 million shares of ViroPharma common stock, which correlates to \$205 million of convertible notes outstanding.

The purchased call options and sold warrants are separate transactions entered into by us with the counterparties, are not part of the terms of the senior convertible notes, and will not affect the holders' rights under the senior convertible notes. Holders of the senior convertible notes will not have any rights with respect to the purchased call options or the sold warrants. The purchased call options and sold warrants meet the definition of derivatives. These instruments have been determined to be indexed to our own stock and have been recorded in stockholders' equity in our Consolidated Balance Sheet. As long as the instruments are classified in stockholders' equity they are not subject to the mark to market provisions.

Credit Facility

In September, 2011, we entered into a \$200 million, three-year senior secured revolving credit facility (the "Credit Facility"), the terms of which are set forth in a Credit Agreement dated as of September 9, 2011 (the "Credit Agreement") with JPMorgan Chase Bank, N.A., as administrative agent, BMO Harris Financing Inc., TD Bank, N.A. and Morgan Stanley Bank, NA as co-syndication agents and certain other lenders.

The Credit Facility is available for working capital and general corporate purposes, including acquisitions which comply with the terms of the Credit Agreement. The Credit Agreement provides separate sub-limits for letters of credit up to \$20 million and swing line loans up to \$10 million.

The Credit Agreement requires us to maintain (i) a maximum senior secured leverage ratio of less than 2.00 to 1.00, (ii) a maximum total leverage ratio of less than 3.50 to 1.00, (iii) a minimum interest coverage ratio of greater than 3.50 to 1.00 and (iv) minimum liquidity equal to or greater than the sum of \$100 million plus the aggregate amount of certain contingent consideration payments resulting from business acquisitions payable by us within a specified time period. The Credit Agreement also contains certain other usual and customary affirmative and negative covenants, including but not limited to, limitations on capital expenditures, asset sales, mergers and acquisitions, indebtedness, liens, dividends, investments and transactions with affiliates.

Our obligations under the Credit Facility are guaranteed by certain of our domestic subsidiaries (the "Subsidiary Guarantors") and are secured by substantially all of our assets and the assets of the Subsidiary Guarantors. Borrowings under the Credit Facility will bear interest at an amount equal to a rate calculated based on the type of borrowing and our senior secured leverage ratio (as defined in the Credit Agreement) from time to time. For loans (other than swing line loans), we may elect to pay interest based on adjusted LIBOR plus between 2.25% and 2.75% or an Alternate Base Rate (as defined in the Credit Agreement) plus between 1.25% and 1.75%. We will also pay a commitment fee of between 35 to 45 basis points, payable quarterly, on the average daily unused amount of the Credit Facility based on our senior secured leverage ratio from time to time. As of the date of this filing, we have not drawn any amounts under the Credit Facility.

Contractual Obligations

Future contractual obligations and commercial commitments at December 31, 2011 are as follows:

(in thousands)

Contractual Obligations (1)(2)	Total	1 year or less	2-3 years	4-5 years	More than 5 years
Operating leases (3)	\$ 9,867	\$ 1,881	\$ 3,935	\$ 2,927	\$1,124
Senior convertible notes (4)	22,550	4,100	8,200	8,200	2,050
Collaboration agreements (5)	3,876	1,292	2,584	—	—
Purchase obligations (6)	310,404	68,950	140,412	101,042	—
Total	<u>\$346,697</u>	<u>\$76,223</u>	<u>\$155,131</u>	<u>\$112,169</u>	<u>\$3,174</u>

- (1) This table does not include any contingent consideration related to our business combinations. We account for this contingent consideration as a liability and recognize changes in its fair value in operating income. We will continue to recognize such fair value changes in income until the ultimate disposition or settlement of this liability. Nor does this table include any milestone payments under our licensing arrangements. We have several license agreements where we may pay up to \$191 million in milestone payments based on the occurrence of defined events.
- (2) This table does not include various agreements that we have entered into for services with third party vendors, including agreements to conduct clinical trials, to manufacture product candidates, and for consulting and other contracted services due to the cancelable nature of the services. We accrue the costs of these agreements based on estimates of work completed to date. We estimate that approximately (\$20.0) million will be payable in future periods under arrangements in place at December 31, 2011. Of this amount, approximately \$19.3 million has been accrued for work estimated to have been completed as of December 31, 2011 and approximately (\$39.4) million relates to future performance under these arrangement.
- (3) Operating leases represent building and equipment leases.
- (4) These payments represent interest and principal related to our 2% senior convertible notes due March 2017.
- (5) Pursuant to the terms of the ROW Agreement, Sanquin may conduct certain early stage research programs for which we will provide to Sanquin €1,000,000 (approximately \$1.3 million) per year for a period of five years.
- (6) We have committed to purchase up to 240,000 liters of plasma in 2012 and up to 210,000 liters of plasma per year in 2012 through 2015 from our suppliers. Additionally, we are required to purchase a minimum number of units from our third party toll manufacturer. Excluded from these amounts is the manufacturing fee for Cinryze produced under the EU and ROW agreement as the minimum purchase shall be determined by the Joint Steering Committee in 2013.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of December 31, 2011.

Critical Accounting Policies

Our consolidated financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America. Preparing consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and contingent assets and liabilities. Actual results could differ from such estimates. These estimates and assumptions are affected by the application of our accounting policies. Critical policies and practices are both most important to the portrayal of a company's financial condition and results of operations, and require management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effects of matters that are inherently uncertain.

Our summary of significant accounting policies is described in Note 2 to our Consolidated Financial Statements contained in our Annual Report on Form 10-K for the year ended December 31, 2010. However, we consider the following policies and estimates to be the most critical in understanding the more complex judgments that are involved in preparing our consolidated financial statements and that could impact our results of operations, financial position, and cash flows:

- **Product Sales**—Our net sales consist of revenue from sales of our products, Vancocin, Cinryze, Buccolam and Diamorphine, less estimates for chargebacks, rebates, distribution service fees, returns and losses. We recognize revenue for product sales when title and risk of loss has passed to the customer, which is typically upon delivery to the customer, when estimated provisions for chargebacks, rebates, distribution service fees, returns and losses are reasonably determinable, and when collectability is reasonably assured. Revenue from the launch of a new or significantly unique product may be deferred until estimates can be made for chargebacks, rebates and losses and all of the above conditions are met and when the product has achieved market acceptance, which is typically based on dispensed prescription data and other information obtained during the period following launch.

At the end of each reporting period we analyze our estimated channel inventory and we would defer recognition of revenue on product that has been delivered if we believe that channel inventory at a period end is in excess of ordinary business needs. Further, if we believe channel inventory levels are increasing without a reasonably correlating increase in prescription demand, we proactively delay the processing of wholesaler orders until these levels are reduced.

We establish accruals for chargebacks and rebates, sales discounts and product returns. These accruals are primarily based upon the history of Vancocin and for Cinryze they are based on information on payee's obtained from our SP/SD's and CinryzeSolutions. We also consider the volume and price of our products in the channel, trends in wholesaler inventory, conditions that might impact patient demand for our product (such as incidence of disease and the threat of generics) and other factors.

In addition to internal information, such as unit sales, we use information from external resources, which we do not verify, to estimate the Vancocin channel inventory. Our external resources include prescription data reported by IMS Health Incorporated and written and verbal information obtained from our three largest wholesaler customers with respect to their inventory levels. Based upon this information, we believe that inventory held at these warehouses are within normal levels.

Chargebacks and rebates are the most subjective sales related accruals. While we currently have no contracts with private third party payors, such as HMO's, we do have contractual arrangements with governmental agencies, including Medicaid. We establish accruals for chargebacks and rebates related to these contracts in the period in which we record the sale as revenue. These accruals are based upon historical experience of government agencies' market share, governmental contractual prices, our current pricing and then-current laws, regulations and interpretations. We analyze the accrual at least quarterly and adjust the balance as needed. These analyses have been adjusted to reflect the U.S. healthcare reform acts and their affect on governmental contractual prices and rebates. We believe that a 10% change in our estimate of the actual rate of sales subject to governmental rebates would affect our operating income and accruals by approximately \$2.5 million in the period of adjustment.

Annually, as part of our process, we performed an analysis on the share of Vancocin and Cinryze sales that ultimately go to Medicaid recipients and result in a Medicaid rebate. As part of that analysis, we considered our actual Medicaid historical rebates processed, total units sold and fluctuations in channel inventory. We also consider our payee mix for Cinryze based on information obtained at the time of prescription.

Under the PPACA we are required to fund 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients starting on January 1, 2011. For Vancocin sales subject to this discount we recognize this cost using an effective rebate percentage for all sales to Medicare patients throughout the year. For applicable Cinryze sales we recognize this cost at the time of sale for

product expected to be purchased by a Medicare Part D insured patient when we estimate they are within the coverage gap.

Product return accruals are estimated based on Vancocin's history of damage and product expiration returns and are recorded in the period in which we record the sale of revenue. Cinryze has a no returns policy.

- **Impairment of Long-lived Assets**—We test our long-lived fixed and intangible assets for recoverability whenever events occur or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. The impairment test is a two-step test. Under step one we assess the recoverability of an asset (or asset group). The carrying amount of an asset (or asset group) is not recoverable if it exceeds the sum of the undiscounted cash flows expected from the use and eventual disposition of the asset (or asset group). The impairment loss is measured in step two as the difference between the carrying value of the asset (or asset group) and its fair value. Assumptions and estimates used in the evaluation of impairment may affect the carrying value of long-lived assets, which could result in impairment charges in future periods. Such assumptions include, for example, projections of future cash flows and the timing and number of generic/competitive entries into the market, in determining the undiscounted cash flows, and if necessary, the fair value of the asset and whether impairment exists. These assumptions are subjective and could result in a material impact on operating results in the period of impairment.

On an ongoing periodic basis, we evaluate the useful life of intangible assets and determine if any economic, governmental or regulatory event has modified their estimated useful lives.

On August 4, 2009 the FDA's Pharmaceutical Science and Clinical Pharmacology Advisory Committee voted in favor of the component of the OGD's 2008 draft guidelines on bioequivalence for Vancocin that permits bioequivalence to be demonstrated through comparable in vitro dissolution for potential vancomycin HCl capsule generic products that contain the same active and inactive ingredients in the same amounts as Vancocin, among other requirements. If FDA's proposed bioequivalence method for Vancocin becomes effective, the time period in which a generic competitor could be approved would be reduced and multiple generics may enter the market, which would materially impact our operating results, cash flows and possibly intangible asset valuations. This could also result in a reduction to the useful life of the Vancocin-related intangible assets. Management currently believes there are no indicators that would require a change in useful life as management believes that Vancocin will continue to be utilized along with generics that may enter the market, and the number of generics and the timing of their market entry is unknown.

A reduction in the useful life, as well as the timing and number of generics, will impact our cash flow assumptions and estimate of fair value, perhaps to a level that could result in an impairment charge. We will continue to monitor the actions of the OGD and consider the effects of our opposition actions and any announcements by generic competitors or other adverse events for additional impairment indicators. We will reevaluate the expected cash flows and fair value of our Vancocin-related assets at such time a triggering event occurs.

- **Impairment of Goodwill and Indefinite-lived Intangible Assets**—We review the carrying value of goodwill and indefinite-lived intangible assets, to determine whether impairment may exist. The goodwill impairment test consists of two steps. The first step compares a reporting unit's fair value to its carrying amount to identify potential goodwill impairment. If the carrying amount of a reporting unit exceeds the reporting unit's fair value, the second step of the impairment test must be completed to measure the amount of the reporting unit's goodwill impairment loss, if any. Step two requires an assignment of the reporting unit's fair value to the reporting unit's assets and liabilities to determine the implied fair value of the reporting unit's goodwill. The implied fair value of the reporting unit's goodwill is then compared with the carrying amount of the reporting unit's goodwill to determine the goodwill impairment loss to be recognized, if any. The impairment test for indefinite-lived intangible assets is a one-step test, which compares the fair value of the intangible asset to its carrying value. If

the carrying value exceeds its fair value, an impairment loss is recognized in an amount equal to the excess. Based on accounting standards, it is required that these assets be assessed at least annually for impairment unless a triggering event occurs between annual assessments which would then require an assessment in the period which a triggering event occurred.

- **Share-Based Payments**—We record the estimated grant date fair value of awards granted as stock-based compensation expense in our consolidated statements of operations over the requisite service period, which is generally the vesting period.
- **Income Taxes**—Our annual effective tax rate is based on pre-tax earnings, enacted tax laws and statutory tax rates, determination of manufacturing income and related deduction limits, limitations on the use of tax credits and net operating loss carryforwards, evaluation of qualified expenses related to the orphan drug credit and tax planning opportunities available in the jurisdictions in which we operate. Significant judgment is required in determining our effective tax rate.

On a periodic basis, we evaluate the realizability of our deferred tax assets and adjust such amounts in light of changing facts and circumstances, including but not limited to projections of future taxable income, the reversal of deferred tax liabilities, tax legislation, rulings by relevant tax authorities, tax planning strategies and the progress of ongoing tax examinations. As part of this evaluation, we consider whether it is more likely than not that all or some portion of the deferred tax asset will not be realized. The ultimate realization of a deferred tax asset is dependent upon the generation of future taxable income during the period in which the related temporary difference becomes deductible or the NOL and credit carryforwards can be utilized. With respect to the reversal of valuation allowances, we consider the level of past and future taxable income, the existence and nature of reversing deferred tax liabilities, the utilization of carryforwards and other factors. Revisions to the estimated net realizable value of the deferred tax asset could cause our provision for income taxes to vary significantly from period to period.

We recognize the benefit of tax positions that we have taken or expect to take on the income tax returns we file if such tax position is more likely than not of being sustained. Settlement of filing positions that may be challenged by tax authorities could impact our income tax expense in the year of resolution.

- **Acquisition Accounting**—The application of the purchase accounting requires certain estimates and assumptions especially concerning the determination of the fair values of the acquired intangible assets and property, plant and equipment as well as the liabilities assumed at the date of the acquisition. Moreover, the useful lives of the acquired intangible assets, property, plant and equipment have to be determined.

The total purchase price of businesses acquired will be allocated to the net tangible assets and identifiable intangible assets based on their fair values as of the date of the acquisition and the fair value of any contingent consideration. Changes in the fair value of contingent consideration will be expensed in the period in which the change in fair value occurs. Additionally, acquired IPR&D projects will initially be capitalized and considered indefinite-lived assets subject to annual impairment reviews or more often upon the occurrence of certain events. For those compounds that reach commercialization, the assets are amortized over the expected useful lives.

Measurement of fair value and useful lives are based to a large extent on anticipated cash flows. If actual cash flows vary from those used in calculating fair values, this may significantly affect our future results of operations. In particular, the estimation of discounted cash flows of intangible assets of newly developed products is subject to assumptions closely related to the nature of the acquired products. Factors that may affect the assumptions regarding future cash flows:

- long-term sales forecasts,
- anticipation of selling price erosion after the end of orphan exclusivity due to follow-on biologic competition in the market,
- behavior of competitors (launch of competing products, marketing initiatives etc.).

For significant acquisitions, the purchase price allocation is carried out with assistance from independent third-party valuation specialists. The valuations are based on information available at the acquisition date.

As our business evolves, we may face additional issues that will require increased levels of management estimation and complex judgments.

Recently Issued Accounting Pronouncements

In September 2009, the FASB issued ASU No. 2010-06, Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements. This ASU amends certain disclosure requirements of Topic 820 to provide for additional disclosures for transfers in and out of Levels 1 and 2 and for activity in Level 3. The ASU also clarifies certain other disclosure requirements including level of disaggregation and disclosures around inputs and valuation techniques. We adopted this ASU on January 1, 2010. The new disclosures about the purchases, sales, issuances and settlements in the roll forward activity for Level 3 fair value measurements are effective for fiscal years beginning after December 15, 2010 and we adopted this provision on January 1, 2011. The adoption of this disclosure provision did not have a material impact on our results of operations, cash flows, and financial position.

In October 2009, the FASB issued ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements, or ASU 2009-13, formerly EITF Issue No. 08-1. ASU 2009-13, which amends existing revenue recognition accounting pronouncements that are currently within the scope of FASB ASC Topic 605 and provides accounting principles and application guidance on how the arrangement should be separated, and the consideration allocated. This guidance changes how to determine the fair value of undelivered products and services for separate revenue recognition. Allocation of consideration is now based on management's estimate of the selling price for an undelivered item where there is no other means to determine the fair value of that undelivered item. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. We adopted this ASU January 1, 2011. The adoption of the provisions of this guidance did not have a material impact on our results of operations, cash flows, and financial position.

In March 2010, the FASB ratified EITF Issue No. 08-9, Milestone Method of Revenue Recognition, and as a result of this ratification the FASB issued ASU 2010-17 in April 2010, which states that the milestone method is a valid application of the proportional performance model for revenue recognition if the milestones are substantive and there is substantive uncertainty about whether the milestones will be achieved. The Task Force agreed that whether a milestone is substantive is a judgment that should be made at the inception of the arrangement. To meet the definition of a substantive milestone, the consideration earned by achieving the milestone (1) would have to be commensurate with either the level of effort required to achieve the milestone or the enhancement in the value of the item delivered, (2) would have to relate solely to past performance, and (3) should be reasonable relative to all deliverables and payment terms in the arrangement. No bifurcation of an individual milestone is allowed and there can be more than one milestone in an arrangement. The new guidance is effective for interim and annual periods beginning on or after June 15, 2010. We adopted this ASU January 1, 2011. The adoption of this guidance did not have a material impact on our results of operations, cash flows, and financial position.

In December 2010, the FASB issued ASU 2010-27, Fees Paid to the Federal Government by Pharmaceutical Manufacturers (EITF Issue 10-D; ASC 720), which addresses how pharmaceutical manufacturers should recognize and classify in the income statement fees mandated by the Patient Protection and Affordable Care Act as amended by the Health Care Education Reconciliation Act. The ASU specifies that the liability for the fee be estimated and recorded in full upon the first qualifying sale with a corresponding deferred cost that is amortized to operating expense using a straight-line method of allocation unless another method better allocates the fee over the calendar year. The new guidance is effective for calendar years beginning after December 31, 2010. We adopted this ASU January 1, 2011. The adoption of this guidance does not have a material impact on our results of operations, cash flows, and financial position.

In May 2011, the FASB issued ASU 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs, and the IASB issued IFRS 13, Fair Value Measurement. The new guidance results in a consistent definition of fair value and common requirements for measurement of and disclosure about fair value between U.S. GAAP and IFRS. The ASU is effective for interim and annual periods beginning on or after December 15, 2011, with early adoption prohibited. The new guidance changes certain fair value measurement principles and disclosure requirements. We do not expect the amendment to U.S. GAAP to have a material impact on our results of operations, cash flows, and financial position.

In June 2011, the FASB issued ASU 2011-05, Presentation of Comprehensive Income (Topic 220). This standard eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. The standard is intended to enhance comparability between entities that report under U.S. GAAP and those that report under IFRS, and to provide a more consistent method of presenting non-owner transactions that affect an entity's equity. Under the ASU, an entity can elect to present items of net income and other comprehensive income in one continuous statement, referred to as the statement of comprehensive income, or in two separate, but consecutive, statements. Each component of net income and each component of other comprehensive income, together with totals for comprehensive income and its two parts, net income and other comprehensive income, would need to be displayed under either alternative. The statement(s) would need to be presented with equal prominence as the other primary financial statements. This ASU does not change items that constitute net income and other comprehensive income, when an item of other comprehensive income must be reclassified to net income or the earnings-per-share computation (which will continue to be based on net income). The new U.S. GAAP requirements are effective for public entities as of the beginning of a fiscal year that begins after December 15, 2011 and interim and annual periods thereafter. Early adoption is permitted, but full retrospective application is required under the accounting standard. We do not expect the amendment to U.S. GAAP to have a material impact on our results of operations, cash flows, and financial position.

In December 2011, the FASB issued ASU 2011-12, Deferral of the Effective Date for Amendments to Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update 2011-05. This ASU defers certain provisions of ASU 2011-05, which required entities to present reclassification adjustments out of accumulated other comprehensive income by component in the statement in which net income is presented and the statement in which comprehensive income is presented for both interim and annual periods. This requirement is indefinitely deferred by this ASU and will be further deliberated by the FASB at a future date. The new ASU is effective for public entities as of the beginning of a fiscal year that begins after December 15, 2011 and interim and annual periods thereafter, the same as that for the unaffected provisions of ASU 2011-05. We do not expect the amendments in this ASU to have a material impact on our results of operations, cash flows, and financial position.

In September 2011, the FASB issued ASU 2011-08, Testing Goodwill for Impairment (the revised standard) (Topic 350). The objective of this Update is to simplify how entities test goodwill for impairment. The amendments in the Update provide the option to first assess qualitative factors to determine whether it is necessary to perform the current two-step test. If an entity believes, as a result of its qualitative assessment, that it is more-likely-than-not (a likelihood of more than 50%) that the fair value of a reporting unit is less than its carrying amount, the quantitative impairment test is required. Otherwise, no further testing is required. The revised standard includes examples of events and circumstances that might indicate that a reporting unit's fair value is less than its carrying amount. These include macro-economic conditions such as deterioration in the entity's operating environment, entity-specific events such as declining financial performance, and other events such as an expectation that a reporting unit will be sold. An entity should also consider in its qualitative assessment the "cushion" between a reporting unit's fair value and carrying amount if determined in a recent fair value calculation. The revised standard is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. Early adoption is permitted, if a company has not yet issued financial statements for the most recent annual or interim period, provided that the entity has not yet performed its 2011 annual impairment test. We do not expect the adoption of this guidance to have a material impact on our results of operations, cash flows, and financial position.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

Our holdings of financial instruments are primarily comprised of money market funds holding only U.S. government securities and fixed income securities, including a mix of corporate debt and government securities. All such instruments are classified as securities available for sale. Our debt security portfolio represents funds held temporarily pending use in our business and operations. We manage these funds accordingly. Our primary investment objective is the preservation of principal, while at the same time optimizing the generation of investment income. We seek reasonable assuredness of the safety of principal and market liquidity by investing in cash equivalents (such as Treasury bills and money market funds) and fixed income securities (such as U.S. government and agency securities, municipal securities, taxable municipals, and corporate notes) while at the same time seeking to achieve a favorable rate of return. Our market risk exposure consists principally of exposure to changes in interest rates. Our holdings are also exposed to the risks of changes in the credit quality of issuers. We generally invest in financial instruments with maturities of less than one year. The carrying amount, which approximates fair value based on the level 1 valuation hierarchy of the fair value measurement standard, and the annualized weighted average nominal interest rate of our investment portfolio at December 31, 2011, was approximately \$128.5 million and 0.38%, respectively. The weighted average length to maturity was 7.0 months. A one percent change in the interest rate would have resulted in a \$0.3 million impact to interest income for the quarter ended December 31, 2011.

At December 31, 2011, we had principal outstanding of \$205.0 million of our senior convertible notes. The senior convertible notes bear interest at a rate of 2% per annum, payable semi-annually in arrears on March 15 and September 15 of each year commencing on September 15, 2007. The senior convertible notes are convertible into shares of our common stock at an initial conversion price of \$18.87 per share. The senior convertible notes may only be converted: (i) anytime after December 15, 2016; (ii) during the five business-day period after any five consecutive trading day period (the “measurement period”) in which the price per note for each trading day of that measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such day; (iii) during any calendar quarter (and only during such quarter) after the calendar quarter ending June 30, 2007, if the last reported sale price of our common stock for 20 or more trading days in a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter exceeds 130% of the applicable conversion price in effect on the last trading day of the immediately preceding calendar quarter; or (iv) upon the occurrence of specified corporate events. Upon conversion, holders of the senior convertible notes will receive shares of common stock, subject to our option to irrevocably elect to settle all future conversions in cash up to the principal amount of the senior convertible notes, and shares for any excess. We can irrevocably elect this option at any time on or prior to the 35th scheduled trading day prior to the maturity date of the senior convertible notes. The senior convertible notes may be required to be repaid on the occurrence of certain fundamental changes, as defined in the senior convertible notes. As of December 31, 2011, the fair value of the principal of the \$205.0 million convertible senior notes outstanding was approximately \$318.6 million, based on the level 2 valuation hierarchy of the fair value measurements standard. The carrying value of the debt at December 31, 2011 is \$153.5 million.

In connection with the issuance of the senior convertible senior notes, we have entered into privately-negotiated transactions with two counterparties (the “counterparties”), comprised of purchased call options and warrants sold. These transactions are expected to generally reduce the potential equity dilution of our common stock upon conversion of the senior convertible notes. These transactions expose us to counterparty credit risk for nonperformance. We manage our exposure to counterparty credit risk through specific minimum credit standards, and diversification of counterparties.

Additionally, if we were to utilize amounts under our revolving credit facility, we could be exposed to interest rate risk.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements required by this item are attached to this Report beginning on page 90.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not Applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer, or CEO, and our Chief Financial Officer, or CFO, of the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as of December 31, 2011. Based on that evaluation, our management, including our CEO and CFO, concluded that as of December 31, 2011 our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission and that such information is accumulated and communicated to the Company’s management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

During the quarter ended December 31, 2011, there were no significant changes in our internal control over financial reporting identified in connection with the evaluation of such controls that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control system was designed to provide reasonable assurance to the company’s management and board of directors regarding the preparation and fair presentation of published consolidated financial statements. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company’s assets that could have a material effect on the financial statements.

Our management, including our Chief Executive Officer and Chief Financial Officer, do not expect that our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and implemented, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Further, the design of a control system must reflect the fact that there are resource

constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues within a company are detected. The inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

Our management assessed the effectiveness of its internal control over financial reporting as of December 31, 2011. In making this assessment, it used the criteria based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission in “Internal Control—Integrated Framework” (COSO). Based on our assessments we believe that, as of December 31, 2011, our internal control over financial reporting is effective based on those criteria.

Our independent registered public accounting firm, KPMG LLP, has issued a report on the effectiveness of the Company’s internal control over financial reporting which appears on the next page.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
ViroPharma Incorporated:

We have audited ViroPharma Incorporated's (the Company's) internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control—Integrated Framework issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of the Company as of December 31, 2011 and 2010, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2011, and our report dated February 28, 2012 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Short Hills, New Jersey
February 28, 2012

ITEM 9B. OTHER INFORMATION

Not Applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information concerning our directors and regarding compliance with Section 16 of the Securities Exchange Act of 1934 required by this Item will be set forth in our Proxy Statement, to be filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated by reference to our Proxy Statement.

The information concerning our executive officers required by this Item is incorporated by reference herein to the section of this Annual Report in Part I entitled “Executive Officers of the Registrant”.

Our Board of Directors has adopted a code of business conduct and ethics that applies to our principal executive officers, principal financial officer, and controller, as well as all other employees. A copy of this code of business conduct and ethics has been posted on our Internet website at www.viropharma.com under the investing—corporate governance section. In addition, hard copies can be obtained free of charge through our investor relations department. Any amendments to, or waivers from, a provision of our code of ethics that applies to our principal executive officer, principal financial officer, controller, or persons performing similar functions and that relate to any element of the code of ethics enumerated in paragraph (b) of Item 406 of Regulation S-K shall be disclosed by posting such information on our website.

The information concerning our corporate governance required by this Item will be set forth in our Proxy Statement, to be filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated by reference to our Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item will be set forth in our Proxy Statement, to be filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated by reference to our Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item will be set forth in our Proxy Statement, to be filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated by reference to our Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item will be set forth in our Proxy Statement, to be filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated by reference to our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item will be set forth in our Proxy Statement, to be filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated by reference to our Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Company.(31) (Exhibit 3.1)
3.2	Amended and Restated By-Laws of the Company. (2) (Exhibit 3.3)
4.1	Form of Indenture dated March 19, 2007 between the Company and Wilmington Trust Company, as Trustee. (21) (Exhibit 4.1)
4.2	First Supplemental Indenture, dated as of March 26, 2007, by and between the Company and Wilmington Trust Company, as Trustee. (21) (Exhibit 4.2)
10.1††	Form of Employment Agreement. (14) (Exhibit 10.1)
10.2	Form of Indemnification Agreement. (14) (Exhibit 10.2)
10.3	Investment Agreement among ViroPharma Incorporated and Perseus-Soros Biopharmaceutical Fund, L.P. dated May 5, 1999. (5) (Exhibit 10.20)
10.4††	2001 Equity Incentive Plan. (8) (Exhibit 10.33)
10.5†	License Agreement dated August 8, 2003 by and between GlaxoSmithKline and ViroPharma Incorporated. (4) (Exhibit 10.35)
10.6†	Assignment, Transfer and Assumption Agreement between ViroPharma Incorporated and Eli Lilly and Company dated October 18, 2004.(10) (Exhibit 2.1)
10.7†	Amendment No. 1 to the Assignment, Transfer and Assumption Agreement between ViroPharma Incorporated and Eli Lilly and Company dated November 8, 2004.(10) (Exhibit 2.2)
10.8††	ViroPharma Severance Plan. (14) (Exhibit 10.37)
10.9††	ViroPharma Cash Bonus Plan. (22) (Exhibit 10.2)
10.10††	ViroPharma Board Compensation Policy. (41)
10.11††	Amended and Restated 1995 ViroPharma Stock Option and Restricted Share Plan. (13)
10.12††	2005 Equity Incentive Plan. (19)
10.13††	Form Of Non-Qualified Stock Option Agreement For Members Of The Board Of Directors. (15) (Exhibit 10.2)
10.14††	Form Of Non-Qualified Stock Option Agreement. (15) (Exhibit 10.3)
10.15††	Form of Incentive Stock Option Agreement. (15) (Exhibit 10.4)
10.16†	Master Agreement by and between OSG Norwich Pharmaceuticals, Inc. and ViroPharma Incorporated effective as of December 1, 2005. (16) (Exhibit 10.41)
10.17†	Project Agreement No. 1 by and between OSG Norwich Pharmaceuticals, Inc. and ViroPharma Incorporated. (16) (Exhibit 10.42)
10.18†	Bulk Supply Agreement between ViroPharma and Alpharma Inc. dated April 13, 2006. (17) (Exhibit 10.1)
10.19†	Project Agreement No. 2 by and between OSG Norwich Pharmaceuticals, Inc. and ViroPharma Incorporated dated May 15, 2006. (17) (Exhibit 10.2)
10.20	Real Estate Purchase Agreement between LV Associates, L.P. and the Company dated December 22, 2006. (22) (Exhibit 10.33)

Exhibit No.	Description
10.21	Confirmation of Convertible Bond Hedge Transaction, dated as of March 20, 2007, by and between ViroPharma Incorporated and Credit Suisse International and Credit Suisse, New York Branch, as agent for Credit Suisse International. (21) (Exhibit 10.1)
10.22	Confirmation of Convertible Bond Hedge Transaction, dated as of March 20, 2007, by and between ViroPharma Incorporated and Wells Fargo Bank, National Association. (21) (Exhibit 10.2)
10.23	Confirmation of Issuer Warrant Transaction dated as of March 20, 2007, by and between ViroPharma Incorporated and Credit Suisse International and Credit Suisse, New York Branch, as agent for Credit Suisse International. (21) (Exhibit 10.3)
10.24	Confirmation of Issuer Warrant Transaction, dated as of March 20, 2007, by and between ViroPharma Incorporated and Wells Fargo Bank, National Association.(21) (Exhibit 10.4)
10.25	Amendment to Confirmation of Issuer Warrant Transaction dated as of March 22, 2007, by and between ViroPharma Incorporated and Credit Suisse International and Credit Suisse, New York Branch, as agent for Credit Suisse International. (21) (Exhibit 10.4)
10.26	Amendment to Confirmation of Issuer Warrant Transaction, dated as of March 22, 2007, by and between ViroPharma Incorporated and Wells Fargo Bank, National Association. (21) (Exhibit 10.5)
10.27†	Amended and Restated Bulk Supply Agreement between ViroPharma and Alphanova Inc. dated October 26, 2007.(18) (Exhibit 10.38)
10.28	Agreement and Plan of Merger, dated as of July 15, 2008, by and among ViroPharma Incorporated, HAE Acquisition Corp., and Lev Pharmaceuticals, Inc. (3) (Exhibit 2.1)
10.29	Form of Contingent Value Rights Agreement, by and among ViroPharma Incorporated, Lev Pharmaceuticals, Inc. and StockTrans, Inc. (3) (Exhibit 2.1)
10.30††	Separation Agreement, dated July 15, 2008, by and between Lev Pharmaceuticals, Inc., ViroPharma Incorporated and Joshua Schein. (6) (Exhibit 10.5)
10.31††	Separation Agreement, dated July 15, 2008, by and between Lev Pharmaceuticals, Inc., ViroPharma Incorporated and Judson Cooper. (6) (Exhibit 10.6)
10.32†	Plasma Supply Agreement dated April 12, 2007 (24) (Exhibit 10.4)
10.33†	Agreement for the Purchase and Sale of Blood Plasma dated July 12, 2007 (25)(Exhibit 10.1)
10.34	Lease Agreement with 730 Stockton Drive Associates, L.P. dated March 14, 2008. (27) (Exhibit 10.1)
10.35††	Letter Agreement with Michel de Rosen dated March 30, 2008 (28) (Exhibit 10.1)
10.36††	Letter Agreement between the Company and Robert Pietrusko dated January 9, 2009 (22) (Exhibit 10.1)
10.37	Form of Partial Unwind Agreement with respect to the Note Hedge Transaction Confirmation between ViroPharma Incorporated and Credit Suisse International (32) (Exhibit 10.1)
10.38	Form of Partial Unwind Agreement with respect to the Warrant Confirmation between ViroPharma Incorporated and Credit Suisse International (32) (Exhibit 10.2)
10.39	Form of Partial Unwind Agreement with respect to the Note Hedge Transaction Confirmation between ViroPharma Incorporated and Wells Fargo Bank, National Association (32) (Exhibit 10.3)

Exhibit No.	Description
10.40	Form of Partial Unwind Agreement with respect to the Warrant Confirmation, dated July 11, 2007 between ViroPharma Incorporated and Wells Fargo Bank, National Association (32) (Exhibit 10.4)
10.41††	Amended and Restated ViroPharma Incorporated 2000 Employee Stock Purchase Plan. (33) (Annex A)
10.42††	Form of Amended and Restated Change of Control Agreement with the Executive Officers. (38) (Exhibit 10.1)
10.43†	Intermediate Supply Agreement with Biotest AG dated as of June 19, 2009 by and between ViroPharma SPRL, a wholly owned subsidiary of ViroPharma Incorporated, and Biotest AG. (35) (Exhibit 10.1)
10.44†	First Amendment to the Agreement for the Purchase and Sale of Blood Plasma, dated as of July 9, 2009 by and between ViroPharma Biologics, Inc., a wholly owned subsidiary of ViroPharma Incorporated, and DCI Management Group LLC. (36) (Exhibit 10.1)
10.45†	Manufacturing and Distribution Agreement (Europe and ROW) dated as of January 8, 2010, by and between ViroPharma SPRL, a wholly-owned subsidiary of ViroPharma Incorporated, and Sanquin Bloedvoorziening (Sanquin Blood Supply Foundation) (31) (Exhibit 10.63)
10.46†	Distribution and Manufacturing Services Agreement For the Americas and Israel dated as of January 8, 2010, by and between ViroPharma Biologics, Inc., a wholly-owned subsidiary of ViroPharma Incorporated, and Sanquin Bloedvoorziening (Sanquin Blood Supply Foundation) (31) (Exhibit 10.64)
10.47†	Exclusive License Agreement dated as of February 20, 2006 by and between ViroPharma Incorporated and Dale N. Gerding, M.D. (31) (Exhibit 10.65)
10.48†	Strategic Supply Agreement dated as of February 26, 2010, by and between ViroPharma Biologics, Inc., a wholly-owned subsidiary of ViroPharma Incorporated, and Biotest Pharmaceuticals Corporation. (36)
10.49†	Amendment Number 2 to the Agreement for the Purchase and Sale of Blood Plasma dated as of February 5, 2010, by and between ViroPharma Biologics, Inc., a wholly owned subsidiary of ViroPharma Incorporated and DCI Management Group LLC. (37)
10.50†	Second Amended and Restated Bulk Material Supply Agreement, effective January 1, 2011, by and between ViroPharma Incorporated and Xellia Pharmaceuticals, Inc. (41)
10.51†	Amended and Restated Bulk Material Supply Letter Agreement dated December 14, 2010 by and between ViroPharma Incorporated and Xellia Pharmaceuticals, Inc. (41)
10.52††	Form of Restricted Share Unit Award Agreement. (41)
10.53††	Form of Performance Share Unit Award Agreement (38)
10.54†	Collaboration and License Agreement between ViroPharma SPRL and Halozyme Inc., dated May 10, 2011. (39)
10.55†	Second Amendment to Project Agreement No. 2 between ViroPharma Incorporated and Norwich Pharmaceuticals, Inc., dated May 25, 2011. (39)
10.56	Credit Agreement, dated as of September 9, 2011, among the Company, the lenders named therein, JPMorgan Chase Bank, N.A., as administrative agent, and BMO Harris Financing Inc., TD Bank, N.A. and Morgan Stanley Bank, NA as co-syndication agents. (40)
10.57†	Exclusive License Agreement by and among ViroPharma Incorporated, Intellect Neurosciences, Inc. And Intellect USA, Inc. dated September 29, 2011. (40)

Exhibit No.	Description
10.58†*	Exclusive Clinical Study and Data License Agreement, dated June 12, 2009, by and between ViroPharma Incorporated and Genzyme Corporation.
10.59*	Amendment No. 1 to Exclusive Clinical Study and Data License Agreement, by and between Genzyme Corporation and ViroPharma Incorporated, effective as of October 22, 2009.
10.60†*	Amendment No. 2 to Exclusive Clinical Study and Data License Agreement, by and between Genzyme Corporation and ViroPharma Incorporated, effective as of April 5, 2010.
10.61†*	Share Purchase Agreement, dated October 26, 2011, by and between DuoCort AB and Goldcup 6975 AB.
10.62†*	Development and Option Agreement, dated December 22, 2011, by and between ViroPharma Incorporated and Meritage Pharma, Inc.
14	Code of Conduct and Ethics. (23)(Exhibit 14)
21*	List of Subsidiaries.
23*	Consent of KPMG LLP, Independent Registered Public Accounting Firm.
24*	Power of Attorney (included on signature page).
31.1*	Certification by Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.

† Portions of this exhibit were omitted and filed separately with the Secretary of the Commission pursuant to an application for confidential treatment filed with the Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

†† Compensation plans and arrangements for executives and others.

(1) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended June 30, 2000.

(2) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on November 14, 2008.

(3) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on July 18, 2008.

(4) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended September 30, 2003.

(5) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended March 31, 1999.

(6) Filed as an Exhibit to the Current Report on Form 8-K filed with the Commission on July 18, 2008 by Lev Pharmaceuticals, Inc.

(7) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended March 31, 2001.

(8) Filed as an Exhibit to Registrant's Form 10-K for the year ended December 31, 2001.

(9) Filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the Commission on April 11, 2008.

(10) Filed as an Exhibit to the Company's Current Report on Form 8-K/A filed with the Commission on November 24, 2004.

(11) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on November 29, 2004.

(12) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on February 15, 2005.

- (13) Filed as an Annex to Registrant's Proxy Statement filed with the Commission on April 8, 2002.
- (14) Filed as an Exhibit to Registrant's Form 10-K for the year ended December 31, 2004.
- (15) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended June 30, 2005.
- (16) Filed as an Exhibit to Registrant's Form 10-K for the year ended December 31, 2005.
- (17) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended June 30, 2006.
- (18) Filed as an Exhibit to Registrant's Form 10-K for the year ended December 31, 2008.
- (19) Filed as Annex to Registrant's Proxy Statement filed with the Commission on April 11, 2008.
- (20) Filed as an Exhibit to the Company's Registration Statement on Form S-3 (333-141411) filed with the Commission on March 19, 2007.
- (21) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on March 26, 2007.
- (22) Filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the Commission on January 8, 2009.
- (23) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on February 24, 2010.
- (24) Filed as an Exhibit to Form 10-QSB/A filed by Lev Pharmaceuticals, Inc. on August 27, 2007.
- (25) Filed as an Exhibit to Form 8-K filed by Lev Pharmaceuticals, Inc. on July 25, 2007.
- (26) Filed as an Exhibit to Form 10-Q filed by Lev Pharmaceuticals, Inc. on April 30, 2008.
- (27) Filed as an Exhibit Registrant's Form 10-Q for the quarter ended March 31, 2008.
- (28) Filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the Commission on April 3, 2008.
- (29) Filed as an Exhibit to Form 10-KSB filed by Lev Pharmaceuticals, Inc. on March 31, 2006.
- (30) Filed as an Exhibit to Form 10-KSB filed by Lev Pharmaceuticals, Inc. on March 31, 2006.
- (31) Filed as an Exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 filed with the Commission on February 25, 2010.
- (32) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on March 24, 2009.
- (33) Filed as Annex A to the Company's Proxy Statement filed with the Commission on April 10, 2009.
- (34) Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed with the Commission on July 29, 2009.
- (35) Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed with the Commission on October 29, 2009.
- (36) Filed as an Exhibit to the Company's Amendment No. 1 to Quarterly Report on Form 10-Q for the quarter ended March 31, 2010 filed with the Commission on October 27, 2010.
- (37) Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010 filed with the Commission on April 28, 2010.
- (38) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on January 7, 2010.
- (39) Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed with the Commission on July 28, 2011.
- (40) Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed with the Commission on October 27, 2011.
- (41) Filed as an Exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 filed with the Commission on February 24, 2011.
- 101 The following financial information from this Annual Report on Form 10-K for the fiscal year ended December 31, 2011, formatted in XBRL (Extensible Business Reporting Language) and furnished electronically herewith: (i) the Condensed Consolidated Balance Sheets; (ii) the Consolidated Statements of Operations; (iii) the Consolidated Statements of Comprehensive Income (Loss) (iv) Consolidated Statements of Stockholders' Equity; (v) the Consolidated Statements of Cash Flows; and, (vi) the Notes to the Consolidated Financial Statements.

Copies of the exhibits are available to stockholders from Peter Wolf, Vice President, General Counsel and Secretary, ViroPharma Incorporated, 730 Stockton Drive, Exton, Pennsylvania 19341. There will be a fee to cover the Company's expenses in furnishing the exhibits.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on our behalf by the undersigned, thereunto duly authorized.

VIROPHARMA INCORPORATED

By: /s/ VINCENT J. MILANO
Vincent J. Milano
President, Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Vincent J. Milano and Charles A. Rowland, Jr. as his or her attorney-in-fact, with the full power of substitution, for him or her in any and all capacities, to sign any amendments to this Report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

<u>Name</u>	<u>Capacity</u>	<u>Date</u>
<u>/s/ VINCENT J. MILANO</u> Vincent J. Milano	President, Chief Executive Officer (Principal Executive Officer)	February 28, 2012
<u>/s/ CHARLES A. ROWLAND, JR.</u> Charles A. Rowland, Jr.	Chief Financial Officer (Principal Financial Officer)	February 28, 2012
<u>/s/ RICHARD S. MORRIS</u> Richard S. Morris	Vice President, Chief Accounting Officer (Principal Accounting Officer)	February 28, 2012
<u>/s/ VINCENT J. MILANO</u> Vincent J. Milano	Chairman of the Board	February 28, 2012
<u>/s/ PAUL A. BROOKE</u> Paul A. Brooke	Director	February 28, 2012
<u>/s/ WILLIAM CLAYPOOL, M.D.</u> William Claypool, M.D.	Director	February 28, 2012
<u>/s/ MICHAEL R. DOUGHERTY</u> Michael R. Dougherty	Director	February 28, 2012
<u>/s/ ROBERT J. GLASER</u> Robert J. Glaser	Director	February 28, 2012
<u>/s/ JOHN R. LEONE</u> John R. Leone	Director	February 28, 2012
<u>/s/ JULIE H. MCHUGH</u> Julie H. McHugh	Director	February 28, 2012
<u>/s/ HOWARD H. PIEN</u> Howard H. Pien	Director	February 28, 2012

VIROPHARMA INCORPORATED
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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
ViroPharma Incorporated:

We have audited the accompanying consolidated balance sheets of ViroPharma Incorporated as of December 31, 2011 and 2010, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2011. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of ViroPharma Incorporated as of December 31, 2011 and 2010, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2011, in conformity with U.S. generally accepted accounting principles.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of ViroPharma Incorporated's internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 28, 2012 expressed an unqualified opinion on the effective operation of internal control over financial reporting.

/s/ KPMG LLP

Short Hills, New Jersey
February 28, 2012

ViroPharma Incorporated
Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)	December 31, 2011	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	\$ 331,352	\$ 426,732
Short-term investments	128,478	78,439
Accounts receivable	78,534	43,879
Inventory	60,316	54,388
Prepaid expenses and other current assets	15,059	13,959
Prepaid income taxes	12,137	2,000
Deferred income taxes	10,055	13,744
Total current assets	635,931	633,141
Intangible assets, net	648,659	619,712
Property, equipment and building improvements, net	11,983	11,468
Goodwill	13,184	6,228
Debt issuance costs, net	3,488	2,397
Deferred income taxes	11,786	4,252
Other assets	11,766	10,376
Total assets	<u>\$1,336,797</u>	<u>\$1,287,574</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 11,339	\$ 10,215
Contingent consideration	7,293	10,973
Accrued expenses and other current liabilities	75,983	48,990
Income taxes payable	4,036	1,944
Total current liabilities	98,651	72,122
Other non-current liabilities	1,967	2,463
Contingent consideration	12,896	—
Deferred tax liability, net	178,706	176,111
Long-term debt	153,453	145,743
Total liabilities	<u>445,673</u>	<u>396,439</u>
Stockholders' equity:		
Preferred stock, par value \$0.001 per share. 5,000,000 shares authorized; Series A convertible participating preferred stock; no shares issued and outstanding	—	—
Common stock, par value \$0.002 per share. 175,000,000 shares authorized; issued and outstanding 70,568,501 shares at December 31, 2011 and 78,141,491 shares at December 31, 2010	159	156
Treasury shares, at cost. 9,159,083 shares at December 31, 2011 and 0 shares at December 31, 2010	(169,661)	—
Additional paid-in capital	749,519	717,375
Accumulated other comprehensive loss	(3,414)	(258)
Retained earnings	314,521	173,862
Total stockholders' equity	<u>891,124</u>	<u>891,135</u>
Total liabilities and stockholders' equity	<u>\$1,336,797</u>	<u>\$1,287,574</u>

See accompanying notes to consolidated financial statements.

ViroPharma Incorporated
Consolidated Statements of Operations

(in thousands, except per share data)	Years ended December 31,		
	2011	2010	2009
Revenues:			
Net product sales	\$544,374	\$439,012	\$310,449
Costs and Expenses:			
Cost of sales (excluding amortization of product rights)	79,976	61,288	40,214
Research and development	66,477	39,613	52,083
Selling, general and administrative	127,775	95,664	89,316
Intangible amortization	31,035	29,357	28,183
Goodwill impairment	—	—	65,099
Impairment loss	8,495	—	3,424
Other operating expenses	8,488	1,390	—
Total costs and expenses	322,246	227,312	278,319
Operating income	222,128	211,700	32,130
Other Income (Expense):			
Interest income	655	372	352
Interest expense	(12,640)	(11,616)	(11,609)
Other (expense) income, net	(2,136)	430	—
Gain on long-term debt repurchase	—	—	9,079
Income before income tax expense	208,007	200,886	29,952
Income tax expense	67,348	75,278	41,029
Net income (loss)	140,659	125,608	(11,077)
Net income (loss) per share:			
Basic	\$ 1.89	\$ 1.61	\$ (0.14)
Diluted	\$ 1.68	\$ 1.47	\$ (0.14)
Shares used in computing net income (loss) per share:			
Basic	74,517	77,820	77,423
Diluted	88,076	90,081	77,423

See accompanying notes to consolidated financial statements.

ViroPharma Incorporated**Consolidated Statements of Comprehensive Income (Loss)**

(in thousands)	Year ended December 31,		
	2011	2010	2009
Net income (loss)	\$140,659	\$125,608	\$(11,077)
Other comprehensive income:			
Unrealized losses on available for sale securities, net (1)	(11)	—	—
Cumulative translation adjustment, net	(3,145)	(1,172)	1,569
Comprehensive income (loss)	<u>\$137,503</u>	<u>\$124,436</u>	<u>\$ (9,508)</u>

(1) Net of taxes

See accompanying notes to consolidated financial statements

ViroPharma Incorporated

Consolidated Statements of Stockholders' Equity

(in thousands)	Preferred Stock		Common Stock		Treasury Shares		Additional paid-in capital	Accumulated other comprehensive income (loss)	Retained Earnings	Total stockholders' equity
	Number of shares	Amount	Number of shares	Amount	Number of shares	Amount				
Balance, December 31, 2008	—	\$—	77,398	156	—	\$ —	\$690,502	(655)	59,331	749,334
Exercise of common stock options	—	—	13	—	—	—	22	—	—	22
Employee stock purchase plan	—	—	32	—	—	—	356	—	—	356
Share-based compensation	—	—	—	—	—	—	11,828	—	—	11,828
Stock option tax benefits	—	—	—	—	—	—	44	—	—	44
Cumulative translation adjustment, net	—	—	—	—	—	—	—	1,569	—	1,569
Termination of call spread options, net	—	—	—	—	—	—	274	—	—	274
Repurchase of conversion options on long-term debt	—	—	—	—	—	—	(1,963)	—	—	(1,963)
Net loss	—	—	—	—	—	—	—	—	(11,077)	(11,077)
Balance, December 31, 2009	—	—	77,443	156	—	—	701,063	914	48,254	750,387
Exercise of common stock options	—	—	633	—	—	—	3,342	—	—	3,342
Employee stock purchase plan	—	—	65	—	—	—	202	—	—	202
Share-based compensation	—	—	—	—	—	—	11,172	—	—	11,172
Cumulative translation adjustment, net	—	—	—	—	—	—	—	(1,172)	—	(1,172)
Stock option tax benefits	—	—	—	—	—	—	1,596	—	—	1,596
Net income	—	—	—	—	—	—	—	—	125,608	125,608
Balance, December 31, 2010	—	—	78,141	156	—	—	717,375	(258)	173,862	891,135
Exercise of common stock options	—	—	1,548	3	—	—	14,239	—	—	14,242
Employee stock purchase plan	—	—	38	—	—	—	452	—	—	452
Share-based compensation	—	—	—	—	—	—	14,242	—	—	14,242
Unrealized losses on available for sale securities, net	—	—	—	—	—	—	—	(11)	—	(11)
Cumulative translation adjustment, net	—	—	—	—	—	—	—	(3,145)	—	(3,145)
Repurchase of shares	—	—	(9,159)	—	9,159	(169,661)	—	—	—	(169,661)
Stock option tax benefits	—	—	—	—	—	—	3,211	—	—	3,211
Net income	—	—	—	—	—	—	—	—	140,659	140,659
Balance, December 31, 2011	—	\$—	70,568	\$159	9,159	\$(169,661)	\$749,519	\$(3,414)	\$314,521	\$ 891,124

See accompanying notes to consolidated financial statements.

ViroPharma Incorporated
Consolidated Statements of Cash Flows

(in thousands)	For the years ended December 31,		
	2011	2010	2009
Cash flows from operating activities:			
Net income (loss)	\$ 140,659	\$ 125,608	\$ (11,077)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Non-cash share-based compensation expense	14,242	11,176	11,817
Non-cash asset impairments	8,495	—	3,424
Non-cash interest expense	8,268	7,517	7,291
Change in fair value of contingent consideration	4,664	1,390	—
Gain on long-term debt repurchase	—	—	(9,079)
Non-cash goodwill impairment	—	—	65,099
Deferred tax provision	(19,440)	19,211	28,161
Depreciation and amortization expense	33,467	31,206	29,660
Other, net	5,514	(370)	—
Changes in assets and liabilities, net of businesses acquired:			
Accounts receivable	(34,864)	(2,099)	(26,000)
Inventory	(6,939)	(12,320)	(13,622)
Prepaid expenses and other current assets	(1,801)	(4,277)	(4,447)
Prepaid income taxes/ income taxes payable	(8,034)	1,451	4,447
Other assets	6,616	(4,061)	3,432
Accounts payable	(159)	4,014	(1,489)
Accrued expenses and other current liabilities	26,554	15,565	(2,456)
Payment of contingent consideration	(6,019)	—	—
Other non-current liabilities	(497)	(494)	(382)
Net cash provided by operating activities	170,726	193,517	84,779
Cash flows from investing activities:			
Purchase of DuoCort Pharma AB, net of cash acquired	(32,041)	—	—
Purchase of Auralis, net of cash acquired	—	(13,152)	—
Payment for option purchase right	(7,500)	—	—
Purchase of Vancocin assets	(7,000)	(7,000)	(7,000)
Purchase of property, plant and equipment	(3,007)	(2,807)	(1,929)
Purchase of investments	(152,557)	(86,975)	—
Maturities of investments	101,058	8,000	—
Net cash used in investing activities	(101,047)	(101,934)	(8,929)
Cash flows from financing activities:			
Long-term debt repurchase	—	—	(21,150)
Payment for treasury shares acquired	(169,661)	—	—
Repayment of debt	(292)	(1,575)	—
Payment of financing costs	(1,357)	—	—
Payment of contingent consideration	(9,809)	—	—
Termination of call spread options, net	—	—	274
Net proceeds from issuance of common stock	14,694	3,544	378
Excess tax benefits from share-based payment arrangements	3,211	1,596	44
Net cash (used in) provided by financing activities	(163,214)	3,565	(20,454)
Effect of exchange rate changes on cash	(1,845)	(88)	437
Net (decrease) increase in cash and cash equivalents	(95,380)	95,060	55,833
Cash and cash equivalents at beginning of period	426,732	331,672	275,839
Cash and cash equivalents at end of period	<u>\$ 331,352</u>	<u>\$ 426,732</u>	<u>\$331,672</u>

See accompanying notes to consolidated financial statements.

ViroPharma Incorporated
Notes to the Consolidated Financial Statements

Note 1. Organization and Business Activities

ViroPharma Incorporated and subsidiaries is a global biotechnology company dedicated to the development and commercialization of products that address serious diseases, with a focus on products used by physician specialists or in hospital settings. We intend to grow through sales of our marketed products, through continued development of our product pipeline, expansion of sales into additional territories outside the United States, through potential acquisition or licensing of products and product candidates and the acquisition of companies. We expect future growth to be driven by sales of Vancocin, sales of Cinryze, both domestically and internationally, sales of Buccolam and Plenadren in Europe, and by our primary development programs, including C1 esterase inhibitor and a non-toxicogenic strain of *C. difficile* (VP20621).

We market and sell Cinryze in the United States for routine prophylaxis against angioedema attacks in adolescent and adult patients with hereditary angioedema (HAE). Cinryze is a C1 esterase inhibitor therapy for routine prophylaxis against HAE, also known as C1 inhibitor (C1-INH) deficiency, a rare, severely debilitating, life-threatening genetic disorder. Cinryze was acquired in October 2008 and in January 2010, we acquired expanded rights to commercialize Cinryze and future C1-INH derived products in certain European countries and other territories throughout the world as well as rights to develop future C1-INH derived products for additional indications. In June 2011, the European Commission granted us Centralized Marketing Authorization for Cinryze® in adults and adolescents with HAE for routine prevention, pre-procedure prevention and acute treatment of angioedema attacks. The approval also includes a self administration option for appropriately trained patients. We have begun to commercialize Cinryze in Europe and continue to evaluate our commercialization plans in countries where we have distribution rights.

We also market and sell Vancocin HCl capsules, the oral capsule formulation of vancomycin hydrochloride, in the U.S. and its territories. Vancocin is indicated for the treatment of *C. difficile*-associated diarrhea (CDAD). Vancocin capsules are also used for the treatment of enterocolitis caused by *Staphylococcus aureus*, including methicillin-resistant strains.

On December 14, 2011, we announced the modernization of labeling for Vancocin Capsules made effective through the FDA's approval of a supplemental new drug application (sNDA).

On November 15, 2011, we acquired a 100% ownership interest in DuoCort Pharma AB (DuoCort), a private company based in Helsingborg, Sweden focused on improving glucocorticoid replacement therapy for treatment of adrenal insufficiency, or Addison's disease (AD). We paid approximately 213 million Swedish Krona (SEK) or approximately \$32.1 million in upfront consideration. We have also agreed to make additional payments ranging from SEK 240 million up to SEK 860 million or approximately \$35 million to \$124 million, contingent on the achievement of certain milestones. Up to SEK 160 million or approximately \$24 million of the contingent payments relate to specific regulatory milestones; and up to SEK 700 million or approximately \$105 million of the contingent payments are related to commercial milestones based on the success of the product.

The acquisition of Duocort further expands our orphan disease commercial product portfolio. On November 3, 2011, the European Commission (EC) granted European Marketing Authorization for Plenadren® (hydrocortisone, modified release tablet), an orphan drug for treatment of adrenal insufficiency in adults, which will bring these patients their first pharmaceutical innovation in over 50 years. We anticipate commercial launch of Plenadren in the EU in late 2012 or early 2013. A named patient program is currently available to patients in Europe, which we expect to continue until commercial launch.

In May 2010, we acquired Auralis Limited, a UK based specialty pharmaceutical company. The acquisition of Auralis provides us with the opportunity to accelerate our European commercial systems for potential future

ViroPharma Incorporated
Notes to the Consolidated Financial Statements (continued)

product launches and additional business development acquisitions. In connection with the Auralis acquisition, we acquired Buccolam® (Oromucosal Solution, Midazolam [as hydrochloride]). In September of 2011, the European Commission granted a Centralized Pediatric Use Marketing Authorization (PUMA) for Buccolam, for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from 3 months to less than 18 years of age. We have begun to commercialize Buccolam in Europe.

Our product development portfolio is primarily focused on three programs, C1 esterase inhibitor [human], VP20621 and VP-20629.

We are working on developing further therapeutic uses, potential additional indications in other C1 mediated diseases, and alternative modes of administration for C1 esterase inhibitor. We are currently undertaking studies on the viability of subcutaneous administration of Cinryze. We intend to conduct ViroPharma sponsored studies and investigator-initiated studies (IIS) to identify further therapeutic uses and potentially expand the labeled indication for Cinryze to include other C1 mediated diseases, such as Antibody-Mediated Rejection (AMR) and Delayed Graft Function (DGF). Additionally, in May 2011, Halozyme Therapeutics (Halozyme) granted us an exclusive worldwide license to use Halozyme's proprietary Enhance™ technology, a proprietary drug delivery platform using Halozyme's recombinant human hyaluronidase enzyme (rHuPH20) technology in combination with a C1 esterase inhibitor. We intend to apply rHuPH20 initially to develop an alternative subcutaneous formulation of Cinryze for routine prophylaxis against attacks of HAE. In September 2011, we initiated a Phase 2 study to evaluate the safety, and pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20.

We are also developing VP20621 for the treatment and prevention of CDAD. In May 2011, we initiated a Phase 2 dose-ranging clinical study to evaluate the safety, tolerability, and efficacy of VP 20621 for prevention of recurrence of CDAD in adults previously treated for CDAD.

On September 30, 2011, we entered into a license agreement for the worldwide rights of Intellect Neurosciences, Inc. (INS) to its clinical stage drug candidate, VP-20629, which we expect to develop for the treatment of Friedrich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease. VP-20629, or indole-3-propionic acid, is a naturally occurring, small molecule that has potent anti-oxidant properties that can protect against neurodegenerative disease. In a recent Phase 1 safety and tolerability study conducted in the Netherlands, VP-20629 was demonstrated to be safe and well tolerated at all dose levels tested. We expect to initiate a phase 2 study within 12 to 18 months of the date of this agreement, after completion of longer-term toxicology studies. We intend to file for Orphan Drug Designation upon review of the phase 2 proof of concept data.

Under the terms of the agreement, we have exclusive worldwide rights to develop and commercialize VP-20629 for the treatment, management or prevention of any disease or condition covered by Intellect's patents. We paid INS a \$6.5 million up-front licensing fee and may pay additional milestones up to \$120 million based upon defined events. We will also pay a tiered royalty of up to a maximum percentage of low teens, based on annual net sales.

In addition to these programs, we have several other assets that we may make additional investments in. These investments will be limited and dependent on our assessment of the potential future commercial success of or benefits from the asset. These assets include maribavir for CMV, recombinant C1-INH and other compounds.

On December 22, 2011, we entered into an exclusive development and option agreement with Meritage Pharma, Inc. (Meritage), a private company based in San Diego, CA focused on developing oral budesonide suspension (OBS) as a treatment for eosinophilic esophagitis (EoE). EoE is a newly recognized chronic disease that is

ViroPharma Incorporated
Notes to the Consolidated Financial Statements (continued)

increasingly being diagnosed in children and adults. It is characterized by inflammation and accumulation of a specific type of immune cell, called an eosinophil, in the esophagus. EoE patients may have persistent or relapsing symptoms, which include dysphagia (difficulty in swallowing), nausea, stomach pain, chest pain, heartburn, loss of weight and food impaction.

As consideration for the agreement, we paid an initial \$7.5 million and have the option to provide Meritage up to an additional \$12.5 million for the development of OBS. Meritage will utilize the funding to conduct additional Phase 2 clinical assessment of OBS. We have an exclusive option to acquire Meritage, at our sole discretion, by providing written notice at any time during the period from December 22, 2011 to and including the date that is the earlier of (a) the date that is 30 business days after the later of (i) the receipt of the final study data for the Phase 2 study and (ii) identification of an acceptable clinical end point definition for a pivotal induction study agreed to by the FDA. If we exercise this option, we have agreed to pay \$69.9 million for all of the outstanding capital stock of Meritage. Meritage stockholders could also receive additional payments of up to \$175 million, upon the achievement of certain clinical and regulatory milestones.

We intend to continue to evaluate in-licensing or other opportunities to acquire products in development, or those that are currently on the market. We plan to seek products that treat serious or life threatening illnesses with a high unmet medical need, require limited commercial infrastructure to market, and which we believe will provide both revenue and earnings growth over time.

Note 2. Basis of Presentation

Principles of Consolidation

The consolidated financial statements include the accounts of ViroPharma and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Cash and cash equivalents

We consider all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

Concentration of credit risk

We invest our excess cash and short-term investments in accordance with a policy objective that seeks to ensure both liquidity and safety of principal. The policy limits investments to certain types of instruments issued by the U.S. government and institutions with strong investment grade credit ratings and places restrictions in their terms and concentrations by type and issuer to reduce our credit risk.

The Company has an exposure to credit risk in its trade accounts receivable from sales of product. Vancocin and Buccolam are distributed through wholesalers that sell the product to pharmacies and hospitals and Cinryze is distributed through specialty pharmacy/ specialty distributors (SP/SD's) who then sell and distribute to physicians, hospitals and patients, among others. Five customers represent approximately 87% of our trade accounts receivable at December 31, 2011 and approximately 97% of our 2011 net product sales.

ViroPharma Incorporated
Notes to the Consolidated Financial Statements (continued)

We, in connection with the issuance of the senior convertible senior notes, have entered into privately-negotiated transactions with two counterparties (the “counterparties”), comprised of purchased call options and warrants sold. These transactions will reduce the potential equity dilution of our common stock upon conversion of the senior convertible notes. These transactions expose the Company to counterparty credit risk for nonperformance. The Company manages its exposure to counterparty credit risk through specific minimum credit standards, and diversification of counterparties.

Single source supplier

The company currently outsources all manufacturing of our products to single source manufacturers. A change in these suppliers could cause a delay in manufacturing and a possible loss of sales, which would affect operating results adversely.

Accounts receivable

Accounts receivable are recorded at the invoiced amount, net of related cash discounts, rebates and estimated returns and do not bear interest. At December 31, 2011 and 2010, there was no allowance for doubtful accounts as all net amounts recorded are deemed collectible. We do not have any off-balance sheet exposure related to our customers.

Inventories

Inventories are stated at the lower of cost or market using actual cost. At December 31, 2011 and 2010, inventory consists of finished goods, work-in-process (WIP) and certain starting materials required to produce inventory of finished product.

Property, equipment and building improvements

Property, equipment and building improvements are recorded at cost. Depreciation and amortization are computed on a straight-line basis over the useful lives of the assets or the lease term, whichever is shorter, ranging from three to thirty years.

The Company leases certain of its equipment and facilities under operating leases. Operating lease payments are charged to operations on a straight-lined basis over the related period that such leased assets are utilized in service. Expenditures for repairs and maintenance are expensed as incurred.

Goodwill and Intangible Assets

Goodwill is not amortized, but is evaluated annually for impairment or when indicators of a potential impairment are present. Our impairment testing of goodwill is performed separately from our impairment testing of intangible assets. The goodwill impairment test consists of two steps. The first step compares a reporting unit's fair value to its carrying amount to identify potential goodwill impairment. If the carrying amount of a reporting unit exceeds the reporting unit's fair value, the second step of the impairment test must be completed to measure the amount of the reporting unit's goodwill impairment loss, if any. Step two requires an assignment of the reporting unit's fair value to the reporting unit's assets and liabilities to determine the implied fair value of the reporting unit's goodwill. The implied fair value of the reporting unit's goodwill is then compared with the carrying amount of the reporting unit's goodwill to determine the goodwill impairment loss to be recognized, if any.

ViroPharma Incorporated
Notes to the Consolidated Financial Statements (continued)

During the first quarter of 2009 and as of March 31, 2009, the market capitalization of ViroPharma fell below the carrying value of the our net assets due to the results of our Phase 3 clinical trial evaluating maribavir used as prophylaxis in allogeneic stem cell transplant patients and our decision to discontinue dosing in our Phase 3 trial of maribavir in solid organ (liver) transplant patients. The fact that our market capitalization fell below our carrying value required us to test for impairment of our goodwill and other intangible assets.

Indefinite-lived intangible assets acquired as part of the Auralis acquisition are used in research and development activities (IPR&D) are not amortized, but are evaluated annually for impairment or when indicators of a potential impairment are present. The impairment test for indefinite-lived intangible assets is a one-step test, which compares the fair value of the intangible asset to its carrying value. If the carrying value exceeds its fair value, an impairment loss is recognized in an amount equal to the excess. The fair value of the assets for purposes of the impairment test is based on valuation models that incorporate assumptions and internal projections of expected future cash flows and operating plans. IPR&D assets are initially recognized at fair value and classified as indefinite-lived assets until completion or abandonment of the project at which time a useful life would be determined.

We tested our goodwill during the fourth quarter of 2011 and there was no impairment as a result of the test.

Long-lived intangible assets acquired as part of the Vancocin and Lev acquisitions are being amortized on a straight-line basis over their estimated useful lives of 25 years. The contract rights acquired as part of the Auralis acquisition are being amortized on a straight-line basis over their estimated useful lives of 12 years and the product rights acquired under the Auralis and DuoCort acquisitions are being amortized on a straight-line basis over their estimated useful lives of 10 years. The Company estimated the useful life of the assets by considering competition by products prescribed for the same indication, the likelihood and estimated future entry of non-generic and generic competition with the same or similar indication and other related factors. The factors that drive the estimate of the life are often uncertain and are reviewed on a periodic basis or when events occur that warrant review.

In September of 2011, the European Commission granted a Centralized Pediatric Use Marketing Authorization (PUMA) for Buccolam, for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from 3 months to less than 18 years of age. This asset was previously classified as an IPR&D asset. As a result of this approval we will begin to amortize this asset over its estimated useful life of 10 years.

Due to the approval and launch of Buccolam, coupled with the approval and launch of Cinryze in Europe, we have decided to alter our development and commercialization plans for the remaining Auralis IPR&D asset. The decision resulted in the impairment of the IPR&D asset and the Auralis Contract rights. Accordingly, we recorded a charge of approximately £5.4 million (approximately \$8.5 million) during 2011.

Impairment or Disposal of Long-Lived Assets

The Company assesses the recoverability of long-lived assets for which an indicator of impairment exists, as necessary. Specifically, the Company determines if a long-lived asset or asset group is impaired by comparing the carrying value of these assets to their estimated undiscounted future operating cash flows. If impairment is indicated, a charge is recognized for the difference between the asset's carrying value and fair value.

Revenue recognition

Revenue is recognized when all four of the following criteria are met (1) the Company has persuasive evidence an arrangement exists, (2) the price is fixed and determinable, (3) title has passed, and (4) collection is reasonably assured. The Company's credit and exchange policy includes provisions for return of its product when it (1) has expired, or (2) was damaged in shipment.

ViroPharma Incorporated
Notes to the Consolidated Financial Statements (continued)

Product revenue is recorded upon delivery to either our wholesalers or distributors and when title has passed. Product demand from wholesalers during a given period may not correlate with prescription demand for the product in that period. As a result, the Company periodically estimates and evaluates the wholesalers' inventory position and would defer recognition of revenue on product that has been delivered if the Company believes that channel inventory at a period end is in excess of ordinary business needs and if the Company believes the value of potential returns is materially different than the returns accrual.

Contract revenues are earned and recognized according to the provisions of each agreement. Contract milestone payments related to the achievement of substantive steps or regulatory events in the development process are recognized as revenues upon the completion of the milestone event or requirement. Payments, if any, received in advance of performance under a contract are deferred and recognized as revenue when earned. Up-front licensing fees where the Company has continuing involvement are deferred and amortized over the estimated performance period. Revenue from government grants is recognized as the related performance to which they are related occurs.

Sales Allowances

The Company records appropriate sales allowances upon the recognition of product revenue. The Company's return policy for Vancocin is limited to damaged or expired product. Cinryze has a no return policy. The return allowance is determined based on analysis of the historical rate of returns associated with Vancocin, which is then applied to sales, and is analyzed considering estimated wholesaler inventory and prescriptions. The chargeback and rebate allowances are determined based on analysis of the historical experience of government agencies' market share and governmental contractual prices relative to current selling prices, as well as the payor mix information provided by our wholesalers and from information obtained through Cinryze Solutions.

Customers

We have principally sold our products directly to wholesale drug distributors and specialty pharmacies/ specialty distributors (SP/SD) in the United States who then distribute the product to pharmacies, hospitals, patients, physicians and long-term care facilities, among others. For Vancocin, our customers are wholesalers who then distribute the product to pharmacies, hospitals and long term care facilities, among others. For Cinryze, our customers are specialty pharmacy and specialty distributors (SP/SD) who will distribute the product to physicians, hospitals and patients.

In the fourth quarter of 2011, we have also begun to sell product to drug distributors in Europe who then distribute the product to pharmacies, hospitals, and physicians.

Five wholesalers and/or SP/SD's represent the majority of the Company's consolidated total revenue, as approximated below:

	Percentage of total revenues		
	2011	2010	2009
Customer A	27%	25%	29%
Customer B	24%	24%	25%
Customer C	20%	21%	13%
Customer D	17%	16%	12%
Customer E	9%	10%	—
Total	<u>97%</u>	<u>96%</u>	<u>79%</u>

ViroPharma Incorporated
Notes to the Consolidated Financial Statements (continued)

Research and development expenses and Collaborations

Research and product development costs are expensed as incurred. Reimbursements of research and development costs under cost sharing collaborations are recorded as a reduction of research and development expenses. Research and development costs include costs for discovery research, pre-clinical and clinical trials, manufacture of drug supply, supplies and acquired services, employee-related costs and allocated and direct facility expenses.

We evaluate our collaborative agreements for proper income statement classification based on the nature of the underlying activity. If payments to and from our collaborative partners are not within the scope of other authoritative accounting literature, the income statement classification for these payments is based on a reasonable, rational analogy to authoritative accounting literature that is applied in a consistent manner. Amounts due to our collaborative partners related to development activities are reflected as a research and development expense.

Income taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date.

A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income and the reversal of deferred tax liabilities during the period in which the related temporary difference becomes deductible. The benefit of tax positions taken or expected to be taken in the Company's income tax returns are recognized in the consolidated financial statements if such positions are more likely than not of being sustained.

Use of estimates

The preparation of the Company's consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

Share-based payments

The Company measures the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. All grants under share-based payment programs are accounted for at fair value and that cost is recognized over the period during which an employee is required to provide service in exchange for the award – the requisite service period (vesting period).

Compensation expense for options granted to non-employees is determined in accordance with the standard as the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. Compensation expense for awards granted to non-employees is re-measured each period.

ViroPharma Incorporated
Notes to the Consolidated Financial Statements (continued)

Earnings per share

Basic earnings per share (EPS) is calculated by dividing net income by the weighted average shares of common stock outstanding during the period. Diluted EPS reflects the potential dilution of securities that could share in the earnings, including the effect of dilution to net income of convertible securities, share-based payments and warrants.

Segment information

The Company is managed and operated as one business. The entire business is managed by a single management team that reports to the chief executive officer. There is no segment or business unit management that reviews separate or discrete financial information. The Company does not operate separate lines of business or separate business entities with respect to any of its products or product candidates.

Foreign Currency Translation

The financial statements of the Company's international subsidiaries are translated into U.S. dollars using the exchange rate at each balance sheet date for assets and liabilities, the historical exchange rate for stockholders' equity and an average exchange rate for each period of revenues, expenses, and gain and losses. The functional currency of the Company's non-U.S. subsidiaries is the local currency. Adjustments resulting from the translation of financial statements are reflected in accumulated other comprehensive income. Transaction gains and losses are recorded within operation results.

Subsequent Events

We have evaluated all subsequent events through the date the financial statements were issued, and have not identified any such events.

New Accounting Standards

In September 2009, the FASB issued ASU No. 2010-06, Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements. This ASU amends certain disclosure requirements of Topic 820 to provide for additional disclosures for transfers in and out of Levels 1 and 2 and for activity in Level 3. The ASU also clarifies certain other disclosure requirements including level of disaggregation and disclosures around inputs and valuation techniques. We adopted this ASU on January 1, 2010. The new disclosures about the purchases, sales, issuances and settlements in the roll forward activity for Level 3 fair value measurements are effective for fiscal years beginning after December 15, 2010 and we adopted this provision on January 1, 2011. The adoption of this disclosure provision did not have a material impact on our results of operations, cash flows, and financial position.

In October 2009, the FASB issued ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements, or ASU 2009-13, formerly EITF Issue No. 08-1. ASU 2009-13, which amends existing revenue recognition accounting pronouncements that are currently within the scope of FASB ASC Topic 605 and provides accounting principles and application guidance on how the arrangement should be separated, and the consideration allocated. This guidance changes how to determine the fair value of undelivered products and services for separate revenue recognition. Allocation of consideration is now based on management's estimate of the selling price for an undelivered item where there is no other means to determine the fair value of that undelivered item. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. We adopted this ASU January 1, 2011. The adoption of the provisions of this guidance did not have a material impact on our results of operations, cash flows, and financial position.

ViroPharma Incorporated
Notes to the Consolidated Financial Statements (continued)

In March 2010, the FASB ratified EITF Issue No. 08-9, Milestone Method of Revenue Recognition, and as a result of this ratification the FASB issued ASU 2010-17 in April 2010, which states that the milestone method is a valid application of the proportional performance model for revenue recognition if the milestones are substantive and there is substantive uncertainty about whether the milestones will be achieved. The Task Force agreed that whether a milestone is substantive is a judgment that should be made at the inception of the arrangement. To meet the definition of a substantive milestone, the consideration earned by achieving the milestone (1) would have to be commensurate with either the level of effort required to achieve the milestone or the enhancement in the value of the item delivered, (2) would have to relate solely to past performance, and (3) should be reasonable relative to all deliverables and payment terms in the arrangement. No bifurcation of an individual milestone is allowed and there can be more than one milestone in an arrangement. The new guidance is effective for interim and annual periods beginning on or after June 15, 2010. We adopted this ASU January 1, 2011. The adoption of this guidance did not have a material impact on our results of operations, cash flows, and financial position.

In December 2010, the FASB issued ASU 2010-27, Fees Paid to the Federal Government by Pharmaceutical Manufacturers (EITF Issue 10-D; ASC 720), which addresses how pharmaceutical manufacturers should recognize and classify in the income statement fees mandated by the Patient Protection and Affordable Care Act as amended by the Health Care Education Reconciliation Act. The ASU specifies that the liability for the fee be estimated and recorded in full upon the first qualifying sale with a corresponding deferred cost that is amortized to operating expense using a straight-line method of allocation unless another method better allocates the fee over the calendar year. The new guidance is effective for calendar years beginning after December 31, 2010. We adopted this ASU January 1, 2011. The adoption of this guidance does not have a material impact on our results of operations, cash flows, and financial position.

In May 2011, the FASB issued ASU 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs, *and the IASB* issued IFRS 13, Fair Value Measurement. The new guidance results in a consistent definition of fair value and common requirements for measurement of and disclosure about fair value between U.S. GAAP and IFRS. The ASU is effective for interim and annual periods beginning on or after December 15, 2011, with early adoption prohibited. The new guidance changes certain fair value measurement principles and disclosure requirements. We do not expect the amendment to U.S. GAAP to have a material impact on our results of operations, cash flows, and financial position.

In June 2011, the FASB issued ASU 2011-05, Presentation of Comprehensive Income (Topic 220). This standard eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. The standard is intended to enhance comparability between entities that report under US GAAP and those that report under IFRS, and to provide a more consistent method of presenting non-owner transactions that affect an entity's equity. Under the ASU, an entity can elect to present items of net income and other comprehensive income in one continuous statement, referred to as the statement of comprehensive income, or in two separate, but consecutive, statements. Each component of net income and each component of other comprehensive income, together with totals for comprehensive income and its two parts, net income and other comprehensive income, would need to be displayed under either alternative. The statement(s) would need to be presented with equal prominence as the other primary financial statements. This ASU does not change items that constitute net income and other comprehensive income, when an item of other comprehensive income must be reclassified to net income or the earnings-per-share computation (which will continue to be based on net income). The new US GAAP requirements are effective for public entities as of the beginning of a fiscal year that begins after December 15, 2011 and interim and annual periods thereafter. Early adoption is permitted, but full retrospective application is required under the accounting standard. We do not expect the amendment to U.S. GAAP to have a material impact on our results of operations, cash flows, and financial position.

ViroPharma Incorporated
Notes to the Consolidated Financial Statements (continued)

In December 2011, the FASB issued ASU 2011-12, Deferral of the Effective Date for Amendments to Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update 2011-05. This ASU defers certain provisions of ASU 2011-05, which required entities to present reclassification adjustments out of accumulated other comprehensive income by component in the statement in which net income is presented and the statement in which comprehensive income is presented for both interim and annual periods. This requirement is indefinitely deferred by this ASU and will be further deliberated by the FASB at a future date. The new ASU is effective for public entities as of the beginning of a fiscal year that begins after December 15, 2011 and interim and annual periods thereafter, the same as that for the unaffected provisions of ASU 2011-05. We do not expect the amendments in this ASU to have a material impact on our results of operations, cash flows, and financial position.

In September 2011, the FASB issued ASU 2011-08, Testing Goodwill for Impairment (the revised standard) (Topic 350). The objective of this Update is to simplify how entities test goodwill for impairment. The amendments in the Update provide the option to first assess qualitative factors to determine whether it is necessary to perform the current two-step test. If an entity believes, as a result of its qualitative assessment, that it is more-likely-than-not (a likelihood of more than 50%) that the fair value of a reporting unit is less than its carrying amount, the quantitative impairment test is required. Otherwise, no further testing is required. The revised standard includes examples of events and circumstances that might indicate that a reporting unit's fair value is less than its carrying amount. These include macro-economic conditions such as deterioration in the entity's operating environment, entity-specific events such as declining financial performance, and other events such as an expectation that a reporting unit will be sold. An entity should also consider in its qualitative assessment the "cushion" between a reporting unit's fair value and carrying amount if determined in a recent fair value calculation. The revised standard is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. Early adoption is permitted, if a company has not yet issued financial statements for the most recent annual or interim period, provided that the entity has not yet performed its 2011 annual impairment test. We do not expect the adoption of this guidance to have a material impact on our results of operations, cash flows, and financial position.

Note 3. Short-Term Investments

Short-term investments consist of fixed income and debt securities with remaining maturities of greater than three months at the date of purchase. At December 31, 2011, all of our fixed income securities were classified as available for sale investments and measured as level 1 instruments of the fair value measurements standard.

The following summarizes the Company's available for sale investments at December 31, 2011:

(in thousands)	Cost	Gross unrealized gains	Gross unrealized losses	Fair value
Debt securities:				
U.S. Treasury	\$ 48,351	\$14	\$ 3	\$ 48,362
Corporate bonds	80,143	43	70	80,116
	<u>\$128,494</u>	<u>\$57</u>	<u>\$73</u>	<u>\$128,478</u>
Maturities of investments were as follows:				
Less than one year	\$ 99,190	\$42	\$39	\$ 99,193
Greater than one year	29,304	15	34	29,285
Total	<u>\$128,494</u>	<u>\$57</u>	<u>\$73</u>	<u>\$128,478</u>

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Notes to the Consolidated Financial Statements (continued)

Note 4. Inventory

Inventory is stated at the lower of cost or market using actual cost. The following represents the components of the inventory at December 31, 2011 and December 31, 2010:

(in thousands)	December 31, 2011	December 31, 2010
Raw Materials	\$50,045	\$37,994
Work In Process	6,035	10,570
Finished Goods	4,236	5,824
Total	<u>\$60,316</u>	<u>\$54,388</u>

Note 5. Property, Equipment and Building Improvements

Property, equipment and building improvements consists of the following at December 31, 2011 and 2010:

(in thousands)	2011	2010
Land	\$ 156	\$ 156
Building	3,039	3,039
Computers and equipment	12,019	9,953
Leasehold improvements	6,001	5,234
	21,215	18,382
Less: accumulated depreciation and amortization	9,232	6,914
Property, equipment and building improvements, net	<u>\$11,983</u>	<u>\$11,468</u>

During 2009, we reclassified property and a building that was previously held for sale to a held and use long term asset. Accordingly, we adjusted the carrying value of the building to fair value at the time of the reclassification and incurred a \$3.4 million impairment charge related to the building.

The useful life for the major categories of property and equipment are 30 years for the building, 3 to 5 years for computers and equipment and 15 years for building improvements.

Note 6. Intangible Assets

The following represents the balance of the intangible assets at December 31, 2011:

(in thousands)	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets
Cinryze Product rights	\$521,000	\$ 66,554	\$454,446
Vancocin Intangibles	168,099	48,074	120,025
Buccolam Product rights	6,271	209	6,062
Auralis Contract rights	8,938	1,579	7,359
Plenadren Product rights	61,277	510	60,767
Total	<u>\$765,585</u>	<u>\$116,926</u>	<u>\$648,659</u>

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Notes to the Consolidated Financial Statements (continued)

The following represents the balance of the intangible assets at December 31, 2010:

(in thousands)	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets
Cinryze Product rights	\$521,000	\$45,714	\$475,286
Vancocin Intangibles	161,099	39,629	121,470
Auralis Contract rights	12,365	601	11,764
Auralis IPR&D (1)	11,192	—	11,192
Total	<u>\$705,656</u>	<u>\$85,944</u>	<u>\$619,712</u>

(1) Non-amortizing

In December 2008, FDA changed OGD's 2006 bioequivalence recommendation, which we have opposed since its original proposal in March 2006, by issuing draft guidance for establishing bioequivalence to Vancocin which would require generic products that have the same inactive ingredients in the same quantities as Vancocin ("Q1 and Q2 the same"), and that meet certain other conditions, to demonstrate bioequivalence through comparative in vitro dissolution testing. Under this latest proposed method, any generic product that is not Q1 and Q2 the same as Vancocin would need to conduct an in vivo study with clinical endpoints to demonstrate bioequivalence with Vancocin. On August 4, 2009 the FDA's Pharmaceutical Science and Clinical Pharmacology Advisory Committee voted in favor of the OGD's 2008 draft guidelines on bioequivalence for Vancocin.

On December 14, 2011, we announced the modernization of labeling for Vancocin Capsules made effective through the FDA's approval of a supplemental new drug application (sNDA).

Through the sNDA approval, Vancocin's label for the first time includes clinical safety and efficacy data for the use of Vancocin capsules in treating *Clostridium difficile*. Vancocin's labeling now reflects safety and efficacy data from 260 patients with *C. difficile*-associated diarrhea (CDAD) treated with Vancocin in two pivotal studies of Genzyme Corporation's investigational drug, tolevamer. We purchased exclusive rights to the two studies from Genzyme for which we will pay Genzyme royalties of 10 percent, 10 percent and 16 percent on net sales of Vancocin for the three year period following the approval of the sNDA.

As a result of the sNDA approval, we believe Vancocin meets the requirements for three years of exclusivity, and that generic vancomycin capsules will not be approved during this period. Under FDA's regulations, labeling changes based on new clinical investigations that are essential to approval of the sNDA and to which the applicant has exclusive rights may be entitled to three years of exclusivity, and generic drug labeling cannot include information protected by such three-year exclusivity. A generic may seek approval by omitting labeling protected by three-year exclusivity; however, if such omissions render the generic drug less safe or effective, it cannot be approved until the three-year exclusivity expires.

We believe that attempting to omit Vancocin labeling changes protected by exclusivity would render generic versions of Vancocin less safe and effective. However, ultimately, the decision on a grant of three-year exclusivity and its effect on generic vancomycin capsule approvals resides with the FDA.

If FDA's proposed bioequivalence method for Vancocin becomes effective, and either FDA does not agree that our labeling changes made effective through our sNDA warrant exclusivity, or FDA acknowledges such exclusivity but nonetheless determines that generic products would be no less safe or effective in the absence of such labeling changes, then the time period in which a generic competitor could be approved would be reduced and multiple generics may enter the market. The approval of generic copies of Vancocin would materially impact

ViroPharma Incorporated
Notes to the Consolidated Financial Statements (continued)

our operating results, cash flows and possibly intangible asset valuations. This could also result in a reduction to the useful life of the Vancocin-related intangible assets. Management currently believes there are no indicators that would require a change in useful life as management believes that Vancocin will continue to be utilized along with generics that may enter the market, and the number of generics and the timing of their market entry is unknown.

We were obligated to pay Eli Lilly and Company (Lilly) additional purchase price consideration based on net sales of Vancocin within a calendar year through 2011. We accounted for these additional payments as additional purchase price which requires that the additional purchase price consideration is recorded as an increase to the intangible asset of Vancocin and is amortized over the remaining estimated useful life of the intangible asset. In addition, at the time of recording the additional intangible assets, a cumulative adjustment is recorded to accumulated intangible amortization, in addition to ordinary amortization expense, in order to reflect amortization as if the additional purchase price had been paid in November 2004.

As of December 31, 2011, we have paid an aggregate of \$51.1 million to Lilly in additional purchase price consideration, as our net sales of Vancocin surpassed the maximum obligation level of \$65 million in 2005 through 2011. In June 30, 2011, we satisfied our obligations to Lilly to make additional purchase price consideration payments under the purchase agreement.

On May 28, 2010 we acquired Auralis Limited, a UK based specialty pharmaceutical company. With the acquisition of Auralis we added one marketed product and several development assets to our portfolio. We recognized an intangible asset related to certain supply agreements for the marketed product and one of the development assets. Additionally, we recognized in-process research and development (IPR&D) assets related to the development assets which are currently not approved. We determined that these assets meet the criterion for separate recognition as intangible assets and the fair value of these assets have been determined based upon discounted cash flow models. The contract rights acquired as part of the Auralis acquisition are being amortized on a straight-line basis over their estimated useful lives of 12 years and the product rights acquired are being amortized on a straight-line basis over their estimated useful lives of 10 years. In 2011, the European Commission granted a Centralized Pediatric Use Marketing Authorization (PUMA) for Buccolam, for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from 3 months to less than 18 years of age. This asset was previously classified as an IPR&D asset. As a result of this approval we began to amortize this asset over its estimated useful life of 10 years.

Due to the approval and launch of Buccolam, coupled with the approval and launch of Cinryze in Europe, we have decided to alter our development and commercialization plans for the remaining Auralis IPR&D asset. The decision resulted in the impairment of the IPR&D asset and a portion of the Auralis Contract rights. Accordingly, we recorded a charge of approximately £5.4 million (approximately \$8.5 million) during 2011.

On November 15, 2011, we acquired a DuoCort Pharma AB (DuoCort), a company focused on improving glucocorticoid replacement therapy for treatment of adrenal insufficiency, or Addison's Disease (AD). The acquisition of Duocort further expands our orphan disease commercial product portfolio. On November 3, 2011, the European Commission (EC) granted European Marketing Authorization for Plenadren® (hydrocortisone, modified release tablet), an orphan drug for treatment of adrenal insufficiency in adults, which will bring these patients their first pharmaceutical innovation in over 50 years. . We recognized an intangible asset related to the Plenadren product rights. The product rights acquired are being amortized on a straight-line basis over their estimated useful lives of 10 years.

Amortization expense for the years ended December 31, 2011, 2010 and 2009 was \$31.0 million, \$29.4 million and \$28.2 million, respectively.

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Notes to the Consolidated Financial Statements (continued)

Note 7. Goodwill and Goodwill Impairment

During the first quarter of 2009 and as of March 31, 2009, the market capitalization of ViroPharma fell below the carrying value of the our net assets due to the results of our Phase 3 clinical trial evaluating maribavir used as prophylaxis in allogeneic stem cell transplant patients and our decision to discontinue dosing in our Phase 3 trial of maribavir in solid organ (liver) transplant patients. The fact that our market capitalization fell below our carrying value required us to test for impairment of our goodwill and other intangible assets. We conducted this analysis at March 31, 2009 and concluded that our goodwill was impaired due to our market capitalization being below the carrying value of our net assets for an extended period of time. We incurred a \$65.1 million charge in the first quarter related to this goodwill impairment. As a result of this impairment we had no goodwill remaining at December 31, 2009.

In May 2010 we acquired a 100% ownership interest in Auralis Limited, a UK based specialty pharmaceutical company. As a result of this acquisition we recorded initial goodwill of approximately \$5.9 million. The change in goodwill since acquisition is attributable to foreign currency fluctuations.

On November 15, 2011, we acquired a DuoCort Pharma AB (DuoCort), a company focused on improving glucocorticoid replacement therapy for treatment of adrenal insufficiency, or Addison's Disease (AD). As a result of this acquisition we recorded goodwill of approximately \$7.3 million. The change in goodwill since acquisition is attributable to foreign currency fluctuations.

Note 8. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following at December 31, 2011 and 2010:

(in thousands)	December 31, 2011	December 31, 2010
Rebates and returns	\$48,115	\$24,352
Payroll, bonus and employee benefits liabilities	10,470	7,283
Clinical development and research liabilities	4,872	3,964
Selling and commercial liabilities	4,149	2,880
Interest payable	1,375	1,196
Other current liabilities	7,002	9,315
	<u>\$75,983</u>	<u>\$48,990</u>

Note 9. Long-Term Debt

Long-term debt as of December 31, 2011 and December 31, 2010 is summarized in the following table:

(in thousands)	December 31, 2011	December 31, 2010
Senior convertible notes	\$153,453	\$145,743
less: current portion	<u>—</u>	<u>—</u>
Total debt principal	<u>\$153,453</u>	<u>\$145,743</u>

On March 26, 2007, we issued \$250.0 million of 2% senior convertible notes due March 2017 (the "senior convertible notes") in a public offering. Net proceeds from the issuance of the senior convertible notes were \$241.8 million. The senior convertible notes are unsecured unsubordinated obligations and rank equally with any

ViroPharma Incorporated
Notes to the Consolidated Financial Statements (continued)

other unsecured and unsubordinated indebtedness. The senior convertible notes bear interest at a rate of 2% per annum, payable semi-annually in arrears on March 15 and September 15 of each year commencing on September 15, 2007.

The debt and equity components of our senior convertible debt securities are bifurcated and accounted for separately based on the value and related interest rate of a non-convertible debt security with the same terms. The fair value of a non-convertible debt instrument at the original issuance date was determined to be \$148.1 million. The equity (conversion options) component of our convertible debt securities is included in Additional paid-in capital on our Consolidated Balance Sheet and, accordingly, the initial carrying value of the debt securities was reduced by \$101.9 million. Our net income for financial reporting purposes is reduced by recognizing the accretion of the reduced carrying values of our convertible debt securities to their face amount of \$250.0 million as additional non-cash interest expense. Accordingly, the senior convertible debt securities will recognize interest expense at effective rates of 8.0% as they are accreted to par value.

As of December 31, 2011 senior convertible notes representing \$205.0 million of principal debt are outstanding with a carrying value of \$153.5 million and a fair value of approximately \$318.6 million, based on the level 2 valuation hierarchy of the fair value measurements standard.

The senior convertible notes are convertible into shares of our common stock at an initial conversion price of \$18.87 per share. The senior convertible notes may only be converted: (i) anytime after December 15, 2016; (ii) during the five business-day period after any five consecutive trading day period (the “measurement period”) in which the price per note for each trading day of that measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such day; (iii) during any calendar quarter (and only during such quarter) after the calendar quarter ending June 30, 2007, if the last reported sale price of our common stock for 20 or more trading days in a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter exceeds 130% of the applicable conversion price in effect on the last trading day of the immediately preceding calendar quarter; or (iv) upon the occurrence of specified corporate events. Upon conversion, holders of the senior convertible notes will receive shares of common stock, subject to ViroPharma’s option to irrevocably elect to settle all future conversions in cash up to the principal amount of the senior convertible notes, and shares for any excess. We can irrevocably elect this option at any time on or prior to the 35th scheduled trading day prior to the maturity date of the senior convertible notes. The senior convertible notes may be required to be repaid on the occurrence of certain fundamental changes, as defined in the senior convertible notes.

Concurrent with the issuance of the senior convertible notes, we entered into privately-negotiated transactions, comprised of purchased call options and warrants sold, to reduce the potential dilution of our common stock upon conversion of the senior convertible notes. The transactions, taken together, have the effect of increasing the initial conversion price to \$24.92 per share. The net cost of the transactions was \$23.3 million.

The call options allowed ViroPharma to receive up to approximately 13.25 million shares of its common stock at \$18.87 per share from the call option holders, equal to the number of shares of common stock that ViroPharma would issue to the holders of the senior convertible notes upon conversion. These call options will terminate upon the earlier of the maturity dates of the related senior convertible notes or the first day all of the related senior convertible notes are no longer outstanding due to conversion or otherwise. Concurrently, we sold warrants to the warrant holders to receive shares of its common stock at an exercise price of \$24.92 per share. These warrants expire ratably over a 60-day trading period beginning on June 13, 2017 and will be net-share settled.

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Notes to the Consolidated Financial Statements (continued)

The purchased call options are expected to reduce the potential dilution upon conversion of the senior convertible notes in the event that the market value per share of ViroPharma common stock at the time of exercise is greater than \$18.87, which corresponds to the initial conversion price of the senior convertible notes, but less than \$24.92 (the warrant exercise price). The warrant exercise price is 75.0% higher than the price per share of \$14.24 of our common stock on the pricing date. If the market price per share of ViroPharma common stock at the time of conversion of any senior convertible notes is above the strike price of the purchased call options (\$18.87), the purchased call options will entitle us to receive from the counterparties in the aggregate the same number of shares of our common stock as we would be required to issue to the holder of the converted senior convertible notes. Additionally, if the market price of ViroPharma common stock at the time of exercise of the sold warrants exceeds the strike price of the sold warrants (\$24.92), we will owe the counterparties an aggregate of approximately 13.25 million shares of ViroPharma common stock. If we have insufficient shares of common stock available for settlement of the warrants, we may issue shares of a newly created series of preferred stock in lieu of our obligation to deliver common stock. Any such preferred stock would be convertible into 10% more shares of our common stock than the amount of common stock we would otherwise have been obligated to deliver under the warrants.

Initially, the purchased call options and warrants sold with the terms described above were based upon the \$250.0 million offering, and the number of shares we would purchase under the call option and the number of shares we would sell under the warrants was 13.25, to correlate to the \$250.0 million principal amount. On March 24, 2009 we repurchased, in a privately negotiated transaction, \$45.0 million in principal amount of our senior convertible notes due March 2017 for total consideration of approximately \$21.2 million. The repurchase represented 18% of our then outstanding debt and was executed at a price equal to 47% of par value. Additionally, in negotiated transactions, we sold approximately 2.38 million call options for approximately \$1.8 million and repurchased approximately 2.38 million warrants for approximately \$1.5 million which terminated the call options and warrants that were previously entered into by us in March 2007. We recognized a \$9.1 million gain in the first quarter of 2009 as a result of this debt extinguishment. For tax purposes, the gain qualifies for deferral until 2014 in accordance with the provisions of the American Recovery and Reinvestment Act.

As a result of the above negotiated sale and purchase transactions we are now entitled to receive approximately 10.87 million shares of our common stock at \$18.87 from the call option holders and if the market price of ViroPharma common stock at the time of exercise of the sold warrants exceeds the strike price of the sold warrants (\$24.92), will owe the counterparties an aggregate of approximately 10.87 million shares of ViroPharma common stock, which correlates to \$205 million of convertible notes outstanding.

The purchased call options and sold warrants are separate transactions entered into by us with the counterparties, are not part of the terms of the senior convertible notes, and will not affect the holders' rights under the senior convertible notes. Holders of the senior convertible notes will not have any rights with respect to the purchased call options or the sold warrants. The purchased call options and sold warrants meet the definition of derivatives. These instruments have been determined to be indexed to our own stock and have been recorded in stockholders' equity in our Consolidated Balance Sheet. As long as the instruments are classified in stockholders' equity they are not subject to the mark to market provisions.

As of December 31, 2011, we have accrued \$1.2 million in interest payable to holders of the senior convertible notes. Debt issuance costs of \$4.8 million have been capitalized and are being amortized over the term of the senior convertible notes, with an unamortized balance of \$2.0 million at December 31, 2011.

Credit Facility

On September 9, 2011, we entered into a \$200 million, three-year senior secured revolving credit facility (the "Credit Facility"), the terms of which are set forth in a Credit Agreement dated as of September 9, 2011 (the

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“Credit Agreement”) with JPMorgan Chase Bank, N.A., as administrative agent, BMO Harris Financing Inc., TD Bank, N.A. and Morgan Stanley Bank, NA as co-syndication agents and certain other lenders.

The Credit Facility is available for working capital and general corporate purposes, including acquisitions which comply with the terms of the Credit Agreement. The Credit Agreement provides separate sub-limits for letters of credit up to \$20 million and swing line loans up to \$10 million.

The Credit Agreement requires us to maintain (i) a maximum senior secured leverage ratio of less than 2.00 to 1.00, (ii) a maximum total leverage ratio of less than 3.50 to 1.00, (iii) a minimum interest coverage ratio of greater than 3.50 to 1.00 and (iv) minimum liquidity equal to or greater than the sum of \$100,000,000 plus the aggregate amount of certain contingent consideration payments resulting from business acquisitions payable by us within a specified time period. The Credit Agreement also contains certain other usual and customary affirmative and negative covenants, including but not limited to, limitations on capital expenditures, asset sales, mergers and acquisitions, indebtedness, liens, dividends, investments and transactions with affiliates.

Our obligations under the Credit Facility are guaranteed by certain of our domestic subsidiaries (the “Subsidiary Guarantors”) and are secured by substantially all of our assets and the assets of the Subsidiary Guarantors. Borrowings under the Credit Facility will bear interest at an amount equal to a rate calculated based on the type of borrowing and our senior secured leverage ratio (as defined in the Credit Agreement) from time to time. For loans (other than swing line loans), we may elect to pay interest based on adjusted LIBOR plus between 2.25% and 2.75% or an Alternate Base Rate (as defined in the Credit Agreement) plus between 1.25% and 1.75%. We will also pay a commitment fee of between 35 to 45 basis points, payable quarterly, on the average daily unused amount of the Credit Facility based on our senior secured leverage ratio from time to time.

As of the date of this filing, we have not drawn any amounts under the Credit Facility and are in compliance with our covenants.

As of December 31, 2011, we have accrued \$0.2 million in interest expense for the revolver. Financing costs of approximately \$1.6 million incurred to establish the Credit Facility were deferred and are being amortized to interest expense over the life of the Credit Facility, with an unamortized balance of \$1.5 million as of December 31, 2011.

Note 10. Acquisitions, License and Research Agreements

DuoCort Pharma AB Acquisition

On November 15, 2011, we acquired a 100% ownership interest in DuoCort Pharma AB (DuoCort), a private company based in Helsingborg, Sweden focused on improving glucocorticoid replacement therapy for treatment of adrenal insufficiency, or Addison’s disease (AD). We paid approximately 213 million Swedish Krona (SEK) or approximately \$32.1 million in upfront consideration. We have also agreed to make additional payments ranging from SEK 240 million up to SEK 860 million or approximately \$35 million to \$124 million, contingent on the achievement of certain milestones. Up to SEK 160 million or approximately \$23 million of the contingent payments relate to specific regulatory milestones; and up to SEK 700 million or approximately \$101 million of the contingent payments are related to commercial milestones based on the success of the product.

The following tables summarize the consideration transferred to acquire DuoCort and the amounts of identified assets acquired and liabilities assumed at the acquisition date. This allocation of purchase price to assets acquired and liabilities assumed is preliminary and may change when final purchase price allocation is completed.

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Notes to the Consolidated Financial Statements (continued)

The consideration transferred was as follows:

	<u>(in thousands)</u>
Cash	\$32,121
Contingent Consideration	21,027
Total	<u>\$53,148</u>

The total consideration was allocated to the net assets acquired and liabilities assumed as follows:

	<u>(in thousands)</u>
Assets acquired:	
Cash	\$ 80
Inventory	246
Other current assets	591
Product rights	63,821
Goodwill	7,264
Total assets	<u>\$72,002</u>
Liabilities assumed:	
Trade and other payables	\$ 1,721
Loans payable	301
Deferred tax liabilities	16,832
Total liabilities	<u>\$18,854</u>
Consideration transferred	<u>\$53,148</u>

The DuoCourt contingent consideration consists of three separate contingent payments. The first will be payable upon the regulatory approval to manufacture bulk product in the EU. The second contingent payment is based on the attainment of specified revenue targets and the third contingent payment is payable upon regulatory approval of the product in the United States.

The fair value of the first and third contingent consideration payments recognized on the acquisition date was estimated by applying a risk adjusted discount rate to the probability adjusted contingent payments and the expected approval dates. The fair value of the second contingent consideration payment recognized on the acquisition date was estimated by applying a risk adjusted discount rate to the potential payments resulting from probability weighted revenue projections and expected revenue target attainment dates.

These fair values are based on significant inputs not observable in the market, which are referred to in the guidance as Level 3 inputs. The contingent considerations are classified as liabilities and are subject to the recognition of subsequent changes in fair value through our results of operations.

The fair value of the product rights asset has been determined using an income approach based upon a discounted cash flow model. That measure is based on significant inputs not observable in the market, which are referred to in the guidance as Level 3 inputs. Key assumptions include a discount rate of 20.5%, the weighted average cost of capital implied by DuoCort's business enterprise value, and probability weighted cash flows.

The fair value of inventory represents net realizable value for finished goods less a normal profit on selling efforts. The fair value of the remaining assets and liabilities acquired are based on the price that would be received on the sale of the asset or the price paid to transfer the liability to a market participant and approximates its carrying value on the measurement date.

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As a result of the transaction, we recognized \$7.3 million of goodwill which is not deductible for tax purposes.

The DuoCort results of operations have been included in the Consolidated Statement of Operations beginning November 15, 2011.

The results of operations of DuoCort since the acquisition date and had the acquisition occurred on January 1, 2011 are immaterial to our consolidated results of operation. We incurred approximately \$1.4 million of transaction cost as part of this acquisition.

Meritage Pharma, Inc.

On December 22, 2011, entered into an exclusive development and option agreement with Meritage Pharma, Inc. (Meritage), a private development-stage company based in San Diego, CA is focused on developing oral budesonide suspension (OBS) as a treatment for eosinophilic esophagitis (EoE). EoE is a newly recognized chronic disease that is increasingly being diagnosed in children and adults. It is characterized by inflammation and accumulation of a specific type of immune cell, called an eosinophil, in the esophagus. EoE patients may have persistent or relapsing symptoms, which include dysphagia (difficulty in swallowing), nausea, stomach pain, chest pain, heartburn, loss of weight and food impaction.

As consideration for the agreement, we made an initial \$7.5 million non-refundable payment to Meritage and have the option to provide Meritage up to an additional \$12.5 million for the development of OBS. Meritage will utilize the funding to conduct additional Phase 2 clinical assessment of OBS. We have an exclusive option to acquire Meritage, at our sole discretion, by providing written notice at any time during the period from December 22, 2011 to and including the date that is the earlier of (a) the date that is 30 business days after the later of (i) the receipt of the final study data for the Phase 2 study and (ii) identification of an acceptable clinical end point definition for a pivotal induction study agreed to by the FDA. If we exercise this option, we have agreed to pay \$69.9 million for all of the outstanding capital stock of Meritage. Meritage stockholders could also receive additional payments of up to \$175 million, upon the achievement of certain clinical and regulatory milestones.

We have determined that Meritage is a variable interest entity (VIE), however because we do not have the power to direct the activities of Meritage that most significantly impact its economic performance we are not the primary beneficiary of this VIE at this time. Further, we have no oversight of the day-to-day operations of Meritage, nor do we have sufficient rights or any voting representation to influence the operating or financial decisions of Meritage, nor do we participate on any steering or oversight committees. Therefore, we are not required to consolidate Meritage into our financial statements. This consolidation status could change in the future if the option agreement is exercised, or if other changes occur in the relationship between Meritage and us.

We valued the non-refundable \$7.5 million upfront payment using the cost method. Under the cost method, the fair value of the investment is not estimated if there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value of the investment. As of December 31, 2011, we were not aware of any such adverse effects, as such, no fair value estimate has been prepared. The asset is recorded as an other long-term asset on our balance sheet at December 31, 2011. No similar asset was recorded at December 31, 2010.

Intellect Neurosciences, Inc. License Agreement

On September 30, 2011, we entered into a license agreement for the worldwide rights of Intellect Neurosciences, Inc. (INS) to its clinical stage drug candidate, VP-20629, being developed for the treatment of Friedreich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease. We expect to initiate a phase 2 study

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within 12 to 18 months of the date of this agreement, after completion of longer-term toxicology studies. We intend to file for Orphan Drug Designation upon review of the phase 2 proof of concept data. Under the terms of the agreement, we have exclusive worldwide rights to develop and commercialize VP-20629 for the treatment, management or prevention of any disease or condition covered by Intellect's patents. We paid INS a \$6.5 million up-front licensing fee and may pay additional milestones up to \$120 million based upon defined events. We will also pay a tiered royalty of up to a maximum percentage of low teens, based on annual net sales.

Halozyne Therapeutics License Agreement

In May 2011, Halozyne Therapeutics (Halozyne) granted us an exclusive worldwide license to use Halozyne's proprietary Enhance™ technology, a proprietary drug delivery platform using Halozyne's recombinant human hyaluronidase enzyme (rHuPH20) technology in combination with a C1 esterase inhibitor. We intend to apply rHuPH20 initially to develop a novel subcutaneous formulation of Cinryze for routine prophylaxis against attacks. Under the terms of the license agreement, we paid Halozyne an initial upfront payment of \$9 million. In the fourth quarter of 2011, we made a milestone payment of \$3 million related to the initiation of a Phase 2 study begun in September 2011 to evaluate the safety, and pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20. Pending successful completion of an additional series of clinical and regulatory milestones, anticipated to begin during 2012, we may make further milestone payments to Halozyne which could reach up to an additional \$41 million related to HAE and up to \$30 million of additional milestone payments for three additional indications. Additionally, we will pay an annual maintenance fee of \$1 million to Halozyne until specified events have occurred. Upon regulatory approval, Halozyne will receive up to a 10% royalty on net sales of the combination product utilizing Cinryze and rHuPH20, depending on the existence of a valid patent claim in the country of sale.

Auralis Acquisition

In May 2010 we acquired a 100% ownership interest in Auralis Limited, a UK based specialty pharmaceutical company for approximately \$14.5 million in upfront consideration for the acquisition of the company and its existing pharmaceutical licenses and products. We have also agreed to pay an additional payment of £10 million Pounds Sterling (approximately \$15.5 million based on the December 31, 2010 exchange rate) contingent upon the first regulatory approval of a product in late stage development.

The acquisition provides us with the opportunity to accelerate our European commercial systems, which will be utilized in the commercial launch of Cinryze™ (C1 esterase inhibitor [human]) in Europe if approved, for future product launches and potential additional business development acquisitions. The acquisition also provides immediate revenue from sales of a marketed product in the UK and access to two late stage development products.

In September of 2011, the European Commission granted a Centralized Pediatric Use Marketing Authorization (PUMA) for Buccolam, and accordingly the additional consideration was paid. The U.S. dollar equivalent of the payment was approximately \$15.8 million. The fair value of the contingent consideration recognized on the acquisition date (\$9.0 million) was estimated by applying a discount rate based on an implied rate of return from the acquisition to the risk probability weighted asset cash flows and the expected approval date. This fair value was based on significant inputs not observable in the market, which are referred to in the guidance as Level 3 inputs. The contingent consideration was classified as a liability and was subject to the recognition of subsequent changes in fair value.

The results of Auralis's operations have been included in the Consolidated Statement of Operations beginning June 1, 2010.

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The following tables summarize the consideration transferred to acquire Auralis and the amounts of identified assets acquired and liabilities assumed at the acquisition date.

The purchase price was as follows:

	<u>(in thousands)</u>
Cash	\$14,514
Contingent Consideration	9,000
Total purchase price	<u>\$23,514</u>

The total cost of the acquisition was allocated to Auralis assets acquired and liabilities assumed as follows:

	<u>(in thousands)</u>
Assets acquired:	
Cash	\$ 1,362
Trade receivable	741
Inventory	1,623
Property, plant and equipment	23
Contract rights	11,600
IPR&D	10,500
Goodwill	5,851
Deferred tax assets	317
Total assets	<u>\$32,017</u>
Liabilities assumed:	
Trade and other payables	\$ 519
Loan Payable	1,545
Deferred tax liabilities	6,439
Total liabilities	<u>\$ 8,503</u>
Total purchase price	<u>\$23,514</u>

Sanquin Rest of World (ROW) Agreement

On January 8, 2010 we obtained, as part of the Sanquin ROW Agreement, expanded rights to commercialize Cinryze and future C1-INH derived products in certain European countries and other territories throughout the world as well as rights to develop future C1-INH derived products for additional indications. We have begun to commercialize Cinryze in European countries in which we have distribution rights in 2011.

Lev Pharmaceuticals, Inc. Acquisition

In October 2008, we acquired all the outstanding common stock of Lev Pharmaceuticals, Inc. (Lev). Lev was a biopharmaceutical company focused on developing and commercializing therapeutic products for the treatment of inflammatory diseases. The terms of the merger agreement provided for the conversion of each share of Lev common stock into upfront consideration of \$453.1 million, or \$2.75 per Lev share, comprised of \$2.25 per share in cash and \$0.50 per share in ViroPharma common stock, and contingent consideration (CVR's) of up to \$1.00 per share which may be paid on achievement of certain regulatory and commercial milestones. As of December 31, 2011, only the second CVR as described below remains achievable. The target for the first CVR payment of \$0.50 per share (or \$87.5 million) will not be paid as a third party's human C1 inhibitor product was

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approved for the acute treatment of HAE and granted orphan exclusivity. The second CVR payment of \$0.50 per share (\$87.5 million) becomes payable if Cinryze reaches at least \$600 million in cumulative net product sales by October 2018.

The value of the CVR's has not been included in the cost of the acquisition, as the payment of these amounts was not reasonably assured at that time. Should any of the contingently issued payments be made, that value would be added to the purchase price, in accordance with SFAS 141, Accounting for Business Combinations which was the effective GAAP at the time of the acquisition,

As a result of the acquisition, we obtained Cinryze, a C1 inhibitor, which has been approved by the FDA for routine prophylaxis of hereditary angioedema (HAE) also known as C1 inhibitor deficiency, a rare, severely debilitating, life-threatening genetic disorder. We determined that Cinryze product rights have a fair value of \$521.0 million. The estimated fair value of the identifiable product rights for Cinryze was determined based upon a discounted cash flows model using a discount rate of 19%. Additionally, we have determined that the estimated useful life for the Cinryze product rights is 25 years.

Other Agreements

The Company has entered into various other licensing, research and other agreements. Under these other agreements, the Company is working in collaboration with various other parties. Should any discoveries be made under such arrangements, the Company would be required to negotiate the licensing of the technology for the development of the respective discoveries. There are no significant funding commitments under these other agreements.

Note 11. Stockholder's Equity

Preferred Stock

The Company's Board of Directors has the authority, without action by the holders of common stock, to issue up to 5,000,000 shares of preferred stock from time to time in such series and with such preference and rights as it may designate.

Share Repurchase Program

On March 9, 2011, our Board of Directors authorized the use of up to \$150 million to repurchase shares of our common stock and/or our 2% Senior Convertible Notes due 2017. Purchases may be made by means of open market transactions, block transactions, privately negotiated purchase transactions or other techniques from time to time.

On March 14, 2011, we entered into a three month accelerated share repurchase (ASR) agreement with a large financial institution to repurchase \$50.0 million of our common stock on an accelerated basis. We paid \$50.0 million to the financial institution and received approximately 2.7 million shares under this arrangement at an average purchase price of \$18.74 per share.

During the third quarter of 2011, we reacquired approximately 5.5 million shares at a cost of approximately \$98.9 million or an average price of \$18.04 per share. These purchases effectively completed the repurchase program authorized by our board on March 9, 2011.

On September 14, 2011, our Board of Directors authorized the use of up to an additional \$200 million to repurchase shares of our common stock and/or our 2% Senior Convertible Notes due 2017. Purchases may be made by means of open market transactions, block transactions, privately negotiated purchase transactions or other techniques from time to time.

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During the fourth quarter of 2011, we reacquired approximately 1.0 million shares through open market transactions at a cost of approximately \$20.8 million or an average price of \$20.62 per share.

Note 12. Share-based Compensation

Beginning in 2011, our stock-based compensation program consisted of a combination of: time vesting stock options with graduated vesting over a four year period; performance and market vesting common stock units, or PSUs, tied to the achievement of pre-established company performance metrics and market based goals over a three-year performance period; and, time vesting restricted stock awards, or RSUs, granted to our non-employee directors vesting over a one year period. Grants under our former stock based compensation program consisted only of time vesting stock options.

The fair values of our share-based awards are determined as follows:

- Stock option grants are estimated as of the date of grant using a Black-Scholes option valuation model and compensation expense is recognized over the applicable vesting period;
- PSUs subject to company specific performance metrics, which include both performance and service conditions, are based on the market value of our stock on the date of grant. Compensation expense is based upon the number of shares expected to vest after assessing the probability that the performance criteria will be met. Compensation expense is recognized over the vesting period, adjusted for any changes in our probability assessment;
- PSUs subject to our total shareholder return, or TSR, market metric relative to a peer group of companies, which includes both market and service conditions, are estimated using a Monte Carlo simulation. Compensation expense is based upon the number and value of shares expected to vest. Compensation expense is recognized over the applicable vesting period. All compensation cost for the award will be recognized if the requisite service period is fulfilled, even if the market condition is never satisfied; and,
- Time vesting RSUs are based on the market value of our stock on the date of grant. Compensation expense for time vesting RSUs is recognized over the vesting period.

The vesting period for our stock awards is the requisite service period associated with each grant.

Share-based compensation expense consisted of the following for the years ended December 31, 2011, 2010 and 2009:

	December 31,		
	2011	2010	2009
(in thousands)			
Stock options	\$12,154	\$11,047	\$11,547
Performance shares	1,535	—	—
Restricted shares	401	—	—
Employee Stock Purchase Plan	152	129	270
Total	<u>\$14,242</u>	<u>\$11,176</u>	<u>\$11,817</u>

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Our share-based compensation expense is recorded as follows:

(in thousands)	December 31,		
	2011	2010	2009
Research and development	\$ 3,335	\$ 3,329	\$ 3,192
Selling, general and administrative	10,907	7,847	8,625
Total	<u>\$14,242</u>	<u>\$11,176</u>	<u>\$11,817</u>

We currently have three option plans in place: a 1995 Stock Option and Restricted Share Plan ("1995 Plan"), a 2001 Equity Incentive Plan ("2001 Plan") and a 2005 Stock Option and Restricted Share Plan ("2005 Plan") (collectively, the "Plans"). In September 2005, the 1995 Plan expired and no additional grants will be issued from this plan. The Plans were adopted by our board of directors to provide eligible individuals with an opportunity to acquire or increase an equity interest in the Company and to encourage such individuals to continue in the employment of the Company.

On May 23, 2008, the 2005 Plan was amended and an additional 5,000,000 shares of common stock was reserved for issuance upon the exercise of stock options or the grant of restricted shares or restricted share units. This amendment was approved by stockholders at our Annual Meeting of Stockholders in May of 2010. As of December 31, 2011, there were 4,163,477 shares available for grant under the Plans.

The following table lists information about these equity plans at December 31, 2011:

	1995 Plan	2001 Plan	2005 Plan	Combined
Shares authorized for issuance	4,500,000	500,000	12,850,000	17,850,000
Shares outstanding	4,500,000	500,000	8,686,523	13,686,523
Shares available for grant	<u>—</u>	<u>—</u>	<u>4,163,477</u>	<u>4,163,477</u>

Employee Stock Option Plans

Stock options granted under the 2005 Plan must be granted at an exercise price not less than the fair value of the Company's common stock on the date of grant. Stock options granted under the 2001 Plan can be granted at an exercise price that is less than the fair value of the Company's common stock at the time of grant. Stock options granted under the 1995 Plan were granted at an exercise price not less than the fair value of the Company's common stock on the date of grant. Stock options granted from the Plans are exercisable for a period not to exceed ten years from the date of grant.

Vesting schedules for the stock options vary, but generally vest 25% per year, over four years. Shares issued under the Plans are new shares. The Plans provide for the delegation of certain administrative powers to a committee comprised of company officers.

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Options granted during 2011, 2010 and 2009 had weighted average fair values of \$11.41, \$6.68 and \$6.73 per option. The fair value of each option grant was estimated throughout the year using the Black-Scholes option-pricing model using the following assumptions for the Plans:

	<u>2011</u>	<u>2010</u>	<u>2009</u>
Expected dividend yield	-	-	-
Range of risk free interest rate	1.4% - 2.9%	1.9% - 3.4%	1.6% - 3.4%
Weighted-average volatility	67.8%	71.4%	77.2%
Range of volatility	62.3% - 69.3%	69.3% - 72.4%	71.5% - 79.9%
Range of expected option life (in years)	5.50 - 6.25	5.50 - 6.25	5.50 - 6.25

The risk free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. Volatility is based on the Company's historical stock price using the expected life of the grant.

We estimate forfeiture rates for all share-based awards and monitor stock options exercises and employee termination patterns in estimating the forfeiture rate.

The following table lists option grant activity for the year ended December 31, 2011:

	<u>Share Options</u>	<u>Weighted average exercise price per share</u>
Balance at December 31, 2008	6,301,714	\$10.95
Granted	1,571,009	9.94
Exercised	(51,125)	10.67
Forfeited	(167,062)	11.72
Expired	(64,341)	16.13
Balance at December 31, 2009	7,590,195	10.68
Granted	2,114,784	10.12
Exercised	(649,311)	5.53
Forfeited	(66,393)	10.21
Expired	(435,943)	22.74
Balance at December 31, 2010	8,553,332	10.45
Granted	1,859,778	18.08
Exercised	(1,547,787)	9.20
Forfeited	(274,057)	13.62
Expired	(106,025)	27.47
Balance at December 31, 2011	<u>8,485,241</u>	<u>\$12.03</u>

The total intrinsic value of share options exercised during the year ended December 31, 2011, 2010 and 2009 was approximately \$18.2 million, \$5.9 million and \$0.1 million, respectively.

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We have 8,485,241 option grants outstanding at December 31, 2011 with exercise prices ranging from \$1.00 per share to \$27.21 per share and a weighted average remaining contractual life of 6.79 years. The following table lists the outstanding and exercisable option grants as of December 31, 2011:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding	8,485,241	\$12.03	6.79	\$130,302
Exercisable	4,392,296	\$10.64	5.30	\$ 73,585

As of December 31, 2011, there was \$25.8 million of total unrecognized compensation cost related to unvested share-based payments (including share options) granted under the Plans. That cost is expected to be recognized over a weighted-average period of 2.7 years. The total fair value of shares vested during the year ended December 31, 2011 was \$11.6 million.

Performance Awards

Beginning in 2011, employees receive annual grants of performance award units, or PSUs, in addition to stock options which give the recipient the right to receive common stock that is contingent upon achievement of specified pre-established company performance goals over a three year performance period. The performance goals for the PSUs granted in January 2011, which are accounted for as equity awards, are based upon the following performance measures: (i) our revenue growth over the performance period, (ii) our adjusted net income as a percent of sales at the end of the performance period, and (iii) our relative total shareholder return, or TSR, compared to a peer group of companies at the end of the performance period. Depending on the outcome of these performance goals, a recipient may ultimately earn a number of shares greater or less than their target number of shares granted, ranging from 0% to 200% of the PSUs granted. Shares of our common stock are issued on a one-for-one basis for each PSU earned. Participants vest in their PSUs at the end of the performance period.

The fair value of the market condition PSUs was determined using a Monte Carlo simulation and utilized the following inputs and assumptions:

(in thousands)	December 31, 2011
Closing stock price on grant date	\$17.84
Performance period starting price	\$16.85
Term of award (in years)	2.99
Volatility	69.75%
Risk-free interest rate	1.19%
Expected dividend yield	0.00%
Fair value per TSR PSU	\$24.38

The performance period starting price is measured as the average closing price over the last 30 trading days prior to the performance period start. The Monte Carlo simulation model also assumed correlations of returns of the prices of our common stock and the common stocks of the comparator group of companies and stock price volatilities of the comparator group of companies.

At December 31, 2011, for the purposes of determining stock based compensation we assumed 248,942 and 16,512 performance condition PSUs and TSR based PSUs outstanding, respectively, with weighted-average grant date fair values of \$ 17.84 and \$ 24.38, respectively.

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At December 31, 2011, there was approximately \$3.2 million of unrecognized compensation cost related to all PSUs that is expected to be recognized over a weighted-average period of approximately 2.02 years.

The following table summarizes select information regarding our PSUs as of December 31, 2011:

	<u>Share Units (in thousands)</u>	<u>Weighted- average grant date fair value</u>
Balance at December 31, 2010	—	\$ —
Granted	173,107	18.50
Vested	—	—
Forfeited	(8,415)	18.49
Balance at December 31, 2011	<u>164,692</u>	<u>\$18.50</u>

Restricted Stock Awards

Beginning in 2011, we also grant our non-employee directors restricted stock awards that vest after one year of service. The fair value of a restricted stock award is equal to the closing price of our common stock on the grant date. The following summarizes select information regarding our restricted stock awards as of December 31, 2011:

	<u>Share Units (in thousands)</u>	<u>Weighted- average grant date fair value</u>
Balance at December 31, 2010	—	\$ —
Granted	27,000	17.30
Vested	—	—
Forfeited	—	—
Balance at December 31, 2011	<u>27,000</u>	<u>\$17.30</u>

As of December 31, 2011, there was approximately \$ 0.07 million of unrecognized compensation cost related to RSUs that is expected to be recognized over a weighted average period of 0.14 years.

Employee Stock Purchase Plan

In 2000, the stockholders of the Company approved an employee stock purchase plan. A total of 300,000 shares originally were available under this plan. Since inception of the plan, the stockholders of the Company have approved amendments to the plan to increase the number of shares available for issuance under the plan by 600,000 shares. Under this plan, 29,982, 48,909 and 69,806 shares were sold to employees during 2011, 2010 and 2009. As of December 31, 2011 there are approximately 400,078 shares available for issuance under this plan.

Under this plan, employees may purchase common stock through payroll deductions in semi-annual offerings at a price equal to the lower of 85% of the closing price on the applicable offering commencement date or 85% of the closing price on the applicable offering termination date. Since the total payroll deductions from the plan period are used to purchase shares at the end of the offering period, the number of shares ultimately purchased by the participants is variable based upon the purchase price. Shares issued under the employee stock purchase plan are new shares. There are two plan periods: January 1 through June 30 (“Plan Period One”) and July 1 through December 31 (“Plan Period Two”). The plan qualifies under Section 423 of the Internal Revenue Code.

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the closing price on the applicable offering termination date. Since the total payroll deductions from the plan period are used to purchase shares at the end of the offering period, the number of shares ultimately purchased by the participants is variable based upon the purchase price. Shares issued under the employee stock purchase plan are new shares. There are two plan periods: January 1 through June 30 ("Plan Period One") and July 1 through December 31 ("Plan Period Two"). The plan qualifies under Section 423 of the Internal Revenue Code.

The fair value of the share-based payments was approximately \$152,000. The fair value was estimated using the Type B model, with the following assumptions:

	<u>2011 Plan Period Two</u>	<u>2011 Plan Period One</u>
Risk free interest rate	0.10%	0.19%
Volatility	38.0%	37.8%
Expected option life (in years)	0.5	0.5

Under Plan Period Two, 12,991 shares were sold to employees on December 31, 2011 at \$16.47 per share, which represents the closing price on the offer termination date of \$19.38 per share at 85%.

Under Plan Period One, 16,991 shares were sold to employees on June 30, 2011 at \$15.14 per share, which represents the closing price on the offer termination date of \$17.81 per share at 85%.

Note 13. Income Taxes

For the years ended December 31, 2011, 2010 and 2009, the following table summarizes the components of income before income taxes and the provision for income taxes:

(in thousands)	<u>Year ended December 31,</u>		
	<u>2011</u>	<u>2010</u>	<u>2009</u>
Income (loss) before income taxes:			
Domestic	\$252,381	\$210,819	\$37,020
Foreign	(44,374)	(9,933)	(7,068)
Income before income taxes	<u>\$208,007</u>	<u>\$200,886</u>	<u>\$29,952</u>
Income tax expense (benefit):			
Current:			
Federal	\$ 79,850	\$ 45,727	\$ 7,614
State and local	6,601	9,684	4,018
Foreign	337	(33)	16
Subtotal	<u>86,788</u>	<u>55,378</u>	<u>11,648</u>
Deferred:			
Federal	1,318	26,926	21,588
State and local	(8,136)	(4,198)	10,684
Foreign	(12,622)	(2,828)	(2,891)
Subtotal	<u>(19,440)</u>	<u>19,900</u>	<u>29,381</u>
Income tax expense	<u>\$ 67,348</u>	<u>\$ 75,278</u>	<u>\$41,029</u>
Effective income tax rate	32.4%	37.5%	137.0%

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For the years ended December 31, 2011, 2010 and 2009, the following table reconciles the federal statutory income tax rate to the effective income tax rate:

(% of pre-tax income)	Year ended December 31,		
	2011	2010	2009
U.S. federal statutory income tax rate	35.0%	35.0%	35.0%
State and local income tax, net of federal tax benefit	1.7	1.8	44.3
Share-based compensation	0.3	0.6	5.0
Orphan drug credit	(0.2)	(0.2)	(20.5)
Change in valuation allowance	(2.2)	0.1	(1.6)
Impairments	—	—	75.8
Manufacturing deduction	(4.1)	—	—
Foreign rate differential	1.0	—	—
Other	0.9	0.2	(1.0)
Effective income tax rate	<u>32.4%</u>	<u>37.5%</u>	<u>137.0%</u>

In 2011, 2010 and 2009, respectively, \$3.2 million, \$1.6 million and \$0.1 million related to current stock option tax benefits were allocated directly to stockholders' equity.

The following table summarizes the components of deferred income tax assets and liabilities:

(in thousands)	December 31,	
	2011	2010
Deferred tax assets:		
Net operating loss carryforwards	\$ 17,893	\$ 13,421
Capitalized research and development costs	6,503	6,419
Orphan drug credit carryforward	—	1,482
Research and development credit carryforward	—	3,449
Non-deductible reserves	6,118	5,385
Depreciation	273	670
Intangible asset amortization	11,179	6,965
Equity compensation	10,783	9,770
Other	1,267	1,316
Subtotal	54,016	48,877
Valuation allowance	(4,876)	(6,238)
Deferred tax assets	49,140	42,639
Deferred tax liabilities:		
Intangible asset amortization	198,334	192,963
Convertible note	6,335	6,584
Prepaid expenses	1,388	1,207
Deferred tax liabilities	206,057	200,754
Net deferred tax assets (liability)	<u>\$(156,917)</u>	<u>\$(158,115)</u>

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At December 31, 2011 and 2010, deferred tax assets and liabilities were classified on the Company's balance sheets as follows:

(in thousands)	December 31,	
	2011	2010
Current assets	\$ 10,055	\$ 13,744
Non-current assets	11,786	4,252
Current liabilities	(52)	—
Non-current liabilities	(178,706)	(176,111)
Net deferred tax liability	<u>\$(156,917)</u>	<u>\$(158,115)</u>

The following table summarizes the change in the valuation allowance:

(in thousands)	Year ended December 31,		
	2011	2010	2009
Valuation allowance at beginning of year	\$ 6,238	\$5,949	\$6,436
Tax expense (benefit)	(4,662)	289	(487)
Acquisitions	3,435	—	—
Foreign exchange	(135)	—	—
Valuation allowance at end of year	<u>\$ 4,876</u>	<u>\$6,238</u>	<u>\$5,949</u>

Due to uncertainty regarding the ability to realize the benefit of deferred tax assets relating to certain net operating loss carryforwards, valuation allowances have been established to reduce deferred tax assets to a level that is more likely than not to be realized. Realization of the remaining net deferred tax assets will depend on the generation of sufficient taxable income in the appropriate jurisdiction, the reversal of deferred tax liabilities, tax planning strategies and other factors prior to the expiration date of the carryforwards. A change in the estimates used to make this determination could require a reduction in deferred tax assets if they are no longer considered realizable.

As of December 31, 2011, our foreign subsidiaries have incurred cumulative losses and consequently no deferred tax liability has been established for any future distribution of funds from foreign subsidiaries.

The following table summarizes carryforwards of net operating losses and tax credits as of December 31, 2011.

(in thousands)	Amount	Expiration
Foreign net operating losses	\$ 29,390	Indefinite
State net operating losses	123,381	2020-2028

At December 31, 2011 and 2010, the Company had no gross unrecognized tax benefits. The Company does not expect any material increase or decrease in its gross unrecognized tax benefits during the next twelve months.

The Company and its domestic subsidiaries file consolidated income tax returns in the U.S. and certain states. In addition, separate income tax returns are filed in other states. The Company's foreign subsidiaries file separate income tax returns in the foreign jurisdictions in which they are located. We are not currently under IRS examination. We are currently under examination in a foreign jurisdiction and in certain states for years after 2007. The results of these examinations are not expected to have a material impact on the financial statements.

Our policy is to record interest and penalties related to tax matters in income tax expense.

ViroPharma Incorporated
Notes to the Consolidated Financial Statements (continued)

The Company and its domestic subsidiaries file consolidated income tax returns in the U.S. and certain states. In addition, separate income tax returns are filed in other states. The Company's foreign subsidiaries file separate income tax returns in the foreign jurisdictions in which they are located. We are not currently under IRS examination. We are currently under examination in a foreign jurisdiction and in certain states for years after 2007. The results of these examinations are not expected to have a material impact on the financial statements.

Our policy is to record interest and penalties related to tax matters in income tax expense.

Note 14. Earnings (Loss) per share

(in thousands, except per share data)	For the years ended December 31,		
	2011	2010	2009
Basic Earnings (Loss) Per Share			
Net income (loss)	\$140,659	\$125,608	\$(11,077)
Common stock outstanding (weighted average)	74,517	77,820	77,423
Basic net income (loss) per share	<u>\$ 1.89</u>	<u>\$ 1.61</u>	<u>\$ (0.14)</u>
Diluted Earnings (Loss) Per Share			
Net income (loss)	\$140,659	\$125,608	\$(11,077)
Add interest expense on senior convertible notes, net of income tax	7,548	7,193	—
Diluted net income (loss)	\$148,207	\$132,801	\$(11,077)
Common stock outstanding (weighted average)	74,517	77,820	77,423
Add shares from senior convertible notes	10,864	10,864	—
Add "in-the-money" stock options and stock awards	2,695	1,397	—
Common stock equivalents	88,076	90,081	77,423
Diluted net income (loss) per share	<u>\$ 1.68</u>	<u>\$ 1.47</u>	<u>\$ (0.14)</u>

The following table shows the shares excluded from the calculation of diluted net income per share, as their effect would be anti-dilutive:

(in thousands)	For the years ended December 31,		
	2011	2010	2009
"Out-of-the-money" stock options	1,896	5,447	5,034
Shares from senior convertible notes	—	—	11,406
"In-the-money" stock options	—	—	849

Note 15. Fair Value Measurement

Valuation Hierarchy – GAAP establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

ViroPharma Incorporated
Notes to the Consolidated Financial Statements (continued)

The following tables provide the assets and liabilities carried at fair value measured on a recurring basis as of December 31, 2011 and 2010:

(in thousands of dollars)	Total Carrying Value at December 31, 2011	Fair Value Measurements at December 31, 2011 Using		
		(Level 1)	(Level 2)	(Level 3)
Cash and cash equivalents	\$331,352	\$331,352	\$—	\$ —
Short-term investments	\$128,478	\$128,478	\$—	\$ —
Contingent consideration, short-term	\$ 7,293	\$ —	\$—	\$ 7,293
Contingent consideration, long-term	\$ 12,896	\$ —	\$—	\$12,896

(in thousands of dollars)	Total Carrying Value at December 31, 2010	Fair Value Measurements at December 31, 2010 Using		
		(Level 1)	(Level 2)	(Level 3)
Cash and cash equivalents	\$426,732	\$426,732	\$—	\$ —
Short-term investments	\$ 78,439	\$ 78,439	\$—	\$ —
Contingent consideration	\$ 10,973	\$ —	\$—	\$10,973

The following table provides a rollforward of activity in Level 3:

	(in thousands of dollars)
Balance December 31, 2009	\$ —
Additions	9,000
Re-measurement	1,390
Impact of foreign exchange	583
Settlements	—
Balance December 31, 2010	\$ 10,973
Additions	21,027
Re-measurement	3,711
Impact of foreign exchange	306
Settlements	(15,828)
Balance December 31, 2011	<u>\$ 20,189</u>

Valuation Techniques—Cash and cash equivalents and short-term investments are measured at fair value using quoted market prices and are classified within Level 1 of the valuation hierarchy. There were no changes in valuation techniques during the year ended December 31, 2011.

During the third quarter of 2011, we settled (paid) the contingent consideration liability related to the Auralis acquisition and during the fourth quarter of 2011, we recognized contingent consideration liabilities related to our acquisition of DuoCort.

The fair value of the contingent considerations are measured using significant inputs not observable in the market, which are referred to in the guidance as Level 3 inputs. The fair values are estimated by applying risk adjusted discount rates to the probability adjusted payment amount or to the probability weighted cash flows, assuming an settlement date for the liabilities (probability weighted discounted cash flow methods). There were no changes in the valuation techniques during the period.

ViroPharma Incorporated
Notes to the Consolidated Financial Statements (continued)

We believe that the fair values of our current assets and current liabilities approximate their reported carrying amounts.

Note 16. 401(k) Employee Savings Plan

The Company's 401(k) Employee Savings Plan (the "401(k) Plan") is available to all employees meeting certain eligibility criteria. The 401(k) Plan permits participants to contribute up to 92% of their compensation not to exceed the limits established by the Internal Revenue Code. Participants are always fully vested in their contributions. The Company matches of 25% on the first 6% of participating employee contributions. The Company contributed approximately \$855,000, \$534,000 and \$413,000 to the 401(k) Plan in each of the years ended December 31, 2011, 2010 and 2009, respectively. The Company's contributions are made in cash. The Company's common stock is not an investment option available to participants in the 401(k) Plan.

Note 17. Commitments and Contingencies

We have committed to purchase up to 240,000 liters of plasma in 2012 and up to 210,000 liters of plasma per year in 2012 through 2015 from our suppliers. Additionally, we are required to purchase a minimum number of units from our third party toll manufacturer.

Our future minimum lease payments under our operating leases related to buildings and equipment for periods subsequent to December 31, 2011 are as follows (in thousands):

<u>Year ending December 31,</u>	<u>Commitments</u>
2012	1,881
2013	1,963
2014	1,971
2015	2,000
2016	926
Thereafter	<u>1,126</u>
Total minimum payments	<u>\$9,867</u>

We have severance agreements for certain employees and change of control agreements for executive officers and certain other employees. Under the severance agreements, certain employees may be provided separation benefits from us if they are involuntarily separated from employment. Under our change of control agreements, certain employees are provided separation benefits if they are either terminated or resign for good reason from ViroPharma within 12 months from a change of control.

In addition to the merger consideration paid at closing, Lev shareholders received the non-transferrable contractual right to two contingent payments ("CVR Payments") of \$0.50 each that could deliver up to an additional \$174.6 million, or \$1.00 per share in cash, if Cinryze meets certain targets. The target for the first CVR payment of \$0.50 per share (or \$87.5 million) will not be paid as a third party's human C1 inhibitor product was approved for the acute treatment of HAE and granted orphan exclusivity. The second CVR payment of \$0.50 per share (\$87.5 million) becomes payable if Cinryze reaches at least \$600 million in cumulative net product sales by October 2018. As of December 31, 2011, we have recognized approximately \$525.3 million of cumulative sales of Cinryze.

In connection with the acquisition of DuoCort, we have also agreed to make additional payments ranging from SEK 240 million up to SEK 860 million or approximately \$35 million to \$124 million, contingent on the achievement of certain milestones.

ViroPharma Incorporated
Notes to the Consolidated Financial Statements (continued)

We also have several license agreements where we may pay up to \$191 million in milestone payments based on the occurrence of defined events.

Note 18. Collaborations

In January 2010, we entered into a collaboration agreement with Sanquin to establish a Joint Steering Committee. The Joint Steering Committee shall serve as a forum to establish and discuss progress under, among others, (i) a Global Commercialization Plan; (ii) clinical development programs of ViroPharma and the Sanquin Early Stage Research Programs; (iii) manufacturing Capacity Schedules; (iv) pharmacovigilance matters; (v) quality matters; (vi) manufacturing improvement programs; and (vii) regulatory matters.

Sanquin may conduct certain early stage research programs and we will provide to Sanquin €1,000,000 (approximately \$1.3 million) per year for a period of five years to support such Early Stage Research Programs. We have a right of first refusal to further develop and commercialize the subject matter of each such Early Stage Research Program worldwide (except for the Excluded Territory) subject to Sanquin's and its research partners' right to use any such intellectual property for their internal, non-commercial research purposes. Except for the Early Stage Research Programs, we will be solely responsible for conducting all clinical trials and other development activities necessary to support our efforts to obtain regulatory approval of Cinryze in additional territories as well as any future C1-INH derived products developed pursuant to the Rest of World Agreement. Sanquin has the right to approve any such clinical trials and development activities through the Joint Steering Committee.

Note 19. Supplemental Cash Flow Information

(in thousands)	For the years ended December 31,	
	2011	2010
Supplemental disclosure of non-cash transactions:		
Employee share-based compensation	\$14,242	\$11,176
Unrealized losses on available for sale securities	(11)	—
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	\$93,648	\$52,484
Cash paid for interest	4,141	4,100
Cash received for stock option exercises	14,242	3,342
Cash received for employee stock purchase plan	482	377

ViroPharma Incorporated
Notes to the Consolidated Financial Statements (continued)

Note 20. Quarterly Financial Information (unaudited)

This table summarizes the unaudited consolidated financial results of operations for the quarters ended (amounts in thousands except per share data):

	<u>March 31,</u>	<u>June 30,</u>	<u>September 30,</u>	<u>December 31,</u>
2011 Quarter Ended				
Net product sales	\$127,035	\$128,808	\$142,956	\$145,575
Cost of sales (excluding amortization of product rights)	18,869	21,309	20,115	19,683
Operating expenses	48,131	65,191	63,856	56,597
Impairment loss	—	—	8,495	—
Other income (expense)	365	(2,618)	(5,970)	(5,898)
Income tax expense	23,954	16,894	16,281	10,219
Net income	36,446	22,796	28,239	53,178
Basic net income per share(1)	\$ 0.47	\$ 0.30	\$ 0.38	\$ 0.75
Diluted net income per share(1)	\$ 0.40	\$ 0.28	\$ 0.35	\$ 0.65
2010 Quarter Ended				
Net product sales	\$ 90,647	\$108,961	\$117,781	\$121,623
Cost of sales (excluding amortization of product rights)	13,958	13,641	15,755	17,934
Operating expenses	38,235	42,263	42,790	42,736
Other (expense) income	(3,329)	(6,096)	2,336	(3,725)
Income tax expense	13,843	18,440	23,233	19,762
Net income	21,282	28,521	38,339	37,466
Basic net income per share(1)	\$ 0.27	\$ 0.37	\$ 0.49	\$ 0.48
Diluted net income per share(1)	\$ 0.26	\$ 0.34	\$ 0.45	\$ 0.43

(1) Net income per share amounts may not agree to the per share amounts for the full year due to the use of weighted average shares for each period.

Stockholders' Information

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ANNUAL SHAREHOLDERS' MEETING

The shareholders' meeting will be held on Monday, May 21, 2012 at 10:00 a.m. at The Desmond Hotel and Conference Center, One Liberty Boulevard, Malvern, PA 19355.

SECURITIES INFORMATION

NASDAQ Global Select Market
Symbol: VPHM

TRANSFER AGENT

For shareholder questions regarding lost certificates, address changes, and change of ownership or name in which the shares are held, please direct inquiries to:

StockTrans[®], a Broadridge Company
44 West Lancaster Avenue • Ardmore, PA 19003
Phone: (610) 649.7300
www.stocktrans.com



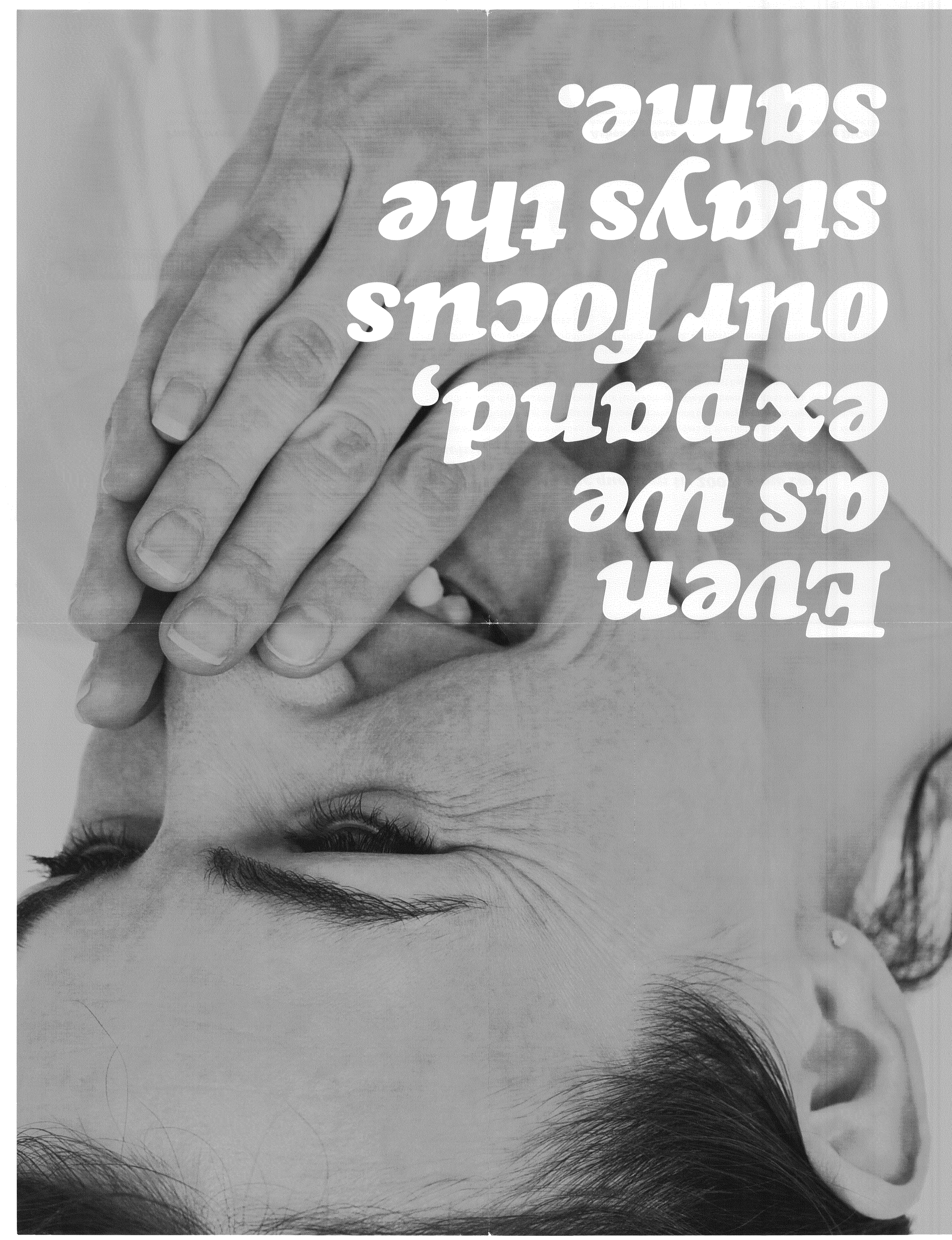
VIROPHARMA INCORPORATED

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www.viropharma.com

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**Even
as we
expand,
our focus
stays the
same.**

OUR GOAL REMAINS CONSTANT:

**Reach more people. Meet more needs.
Make a difference in every patient's life.**

Each one of our patients is a world unto him or herself—a world of children, parents, caregivers, co-workers and neighbors. All of those people are affected by their disease, and all of them benefit when they receive effective treatment. Yes, we are proud of our expansion into Europe, and excited about our prospects in other regions around the globe. But the far-reaching impact we can have on a single patient's life? That's what we live for.

**Steady growth,
extraordinary achievements**

From a financial perspective, our growth has been relentless. 2011 marked the first time in our history that revenues exceeded \$500 million, buoyed by strong growth for both Cinryze® (C1 Esterase

Inhibitor [Human]) and Vancocin® (vancomycin hydrochloride, USP) capsules. In keeping with our commitment to increase shareholder value, we used our capital to repurchase over \$170 million in VPHM shares. But our financial strength goes beyond just providing shareholder value. It allows us to pursue new opportunities for expansion beyond our borders, and ensure that our existing and future patients continue to benefit from ongoing research and innovation.

We're especially proud of the progress we've made in managing patients affected by hereditary angioedema (HAE). More and more of these patients are now receiving preventative therapy for this devastating disease, thanks to Cinryze. As a way of making this therapy accessible

to the widest possible range of appropriate HAE patients, we are expanding our manufacturing capabilities and working hard to develop an alternative way for patients to administer Cinryze. This year we formed a collaboration with Halozyme Therapeutics, a company with an innovative technology to deliver Cinryze subcutaneously, potentially providing an alternative to IV infusion of Cinryze.

Beyond Cinryze, across borders

By securing European approval for Cinryze in 2011, and filing for approval on several other continents, we've begun to expand this therapy's powerful impact into new geographical areas. But we are pleased to report that Cinryze

is no longer the only product following this trajectory. Buccolam® (midazolam oromucosal solution), the first and only licensed oral treatment for convulsive seizures in children and adolescents, was approved in Europe in September, 2011. And in November, Plenadren® (hydrocortisone, modified release tablet) was also approved in Europe, to treat adrenal insufficiency in adults, another rare disease. We expect our European launch of Plenadren to take place in the fourth quarter of 2012.

**More patients,
more unmet needs**

Our drive to meet the needs of more and more patients is keeping our pipeline full of promising products. A large percentage of patients suffering

from recurrent *Clostridium difficile* infections (CDI) have no treatment available to them today; that's why we are determined to advance our candidate VP-20621 as quickly as possible. We also look forward to completing toxicology work on VP-20629, a possible therapy for a rare neurodegenerative disease called Friedreich's Ataxia (FA). And finally, we are conducting a range of studies to explore further uses for the unique properties of C1 esterase inhibitor. Areas of exploration include transplant, demyelination and hematology.

In other words, the possibilities are endless—and considering our remarkable progress in 2011, I have no doubt that we can continue to demonstrate remarkable

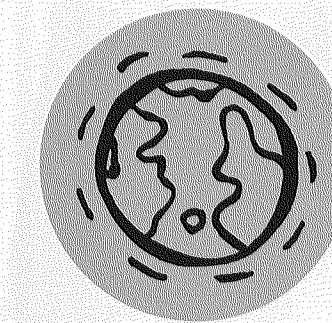
growth in the years to come. We have the right team in place, a suite of promising products to explore, a strong financial position, and amazing patients to inspire us every day. I hope you feel as excited as I am to see what unfolds next.

Out of 2

Vincent J. Milano
March 31, 2012
President, Chief Executive Officer
& Chairman of the Board of Directors

VIROPHARMA INCORPORATED 2017 ANNUAL REPORT

Outward Outward



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www.viropharma.com
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VIROPHARMA
INCORPORATED

CINRYZE

- Filed
- Approved

BUCCOLAM

- Filed
- Approved

PLENADREN

- Filed
- Approved

VANCOCIN

- Filed
- Approved

CANADA

TORONTO, ON

UNITED STATES

EXTON, PA
United States Headquarters

EUROPE

MAIDENHEAD, UK

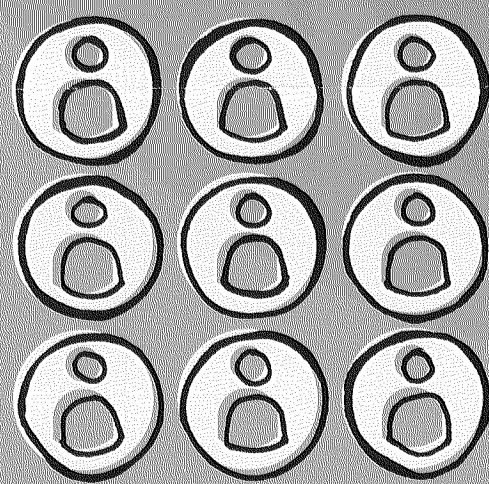
MUNICH, DE

PARIS, FR

BRUSSELS, BE
European Headquarters

MILAN, IT

MADRID, ES



MORE AND MORE
HAE PATIENTS
ARE PREVENTING
THEIR ATTACKS WITH
CINRYZE®
(C1 ESTERASE INHIBITOR [HUMAN])

VIROPHARMA PEOPLE



Paul Firuta
Vice President &
General Manager, Americas



Ramona Rutherford
Director, Human Resources



Ashok Paulose
Application Development Project Manager,
Information Technology



Pam DiCenzo
General Manager, Canada

We first asked the question in 2007: How can we continue to serve small patient populations, while continuing to grow?

The answer was clear: we needed to look beyond the borders of the United States. No matter where you go, no matter what language people speak or what kind of society they live in, there are patients with serious diseases who are desperate for treatment. We have been relentless in our quest to find those patients and bring them hope, and in the past year that quest began to pay off. In 2011 we received two European product approvals for both Cinryze and Buccolam. We also acquired the drug Plenadren, which recently received European approval. In 2012 we will continue our efforts to expand worldwide and offer hope to patients suffering from HAE, epilepsy, adrenal insufficiencies and other rare and devastating diseases.

VP-20621

“Recurrent C. difficile isn’t just frustrating to me as a doctor. It’s defeating for the patient.”

It’s a growing problem: once patients suffering from Clostridium difficile (C. difficile) infection are treated with an effective product like oral Vancomycin, they become vulnerable to re-infection or disease recurrence. According to published literature, approximately 20 to 30 percent of C. difficile infection (CDI) patients will have at least one relapse of the diarrhea that this condition can cause. The goal of our VP-20621 (non-toxigenic C. difficile) program is to prevent these recurrences from happening. VP-20621 works by populating the gastrointestinal tract with a non-toxic strain of bacteria during the vulnerable period after treatment, thus preventing colonization by the toxin-producing C. difficile.

ViroPharma has completed Phase 1 clinical studies of VP-20621, designed to determine the safety and tolerability of the drug. We expect to complete the ongoing Phase 2 evaluation and have results available in 2013.

VP-20629

“My FA patients are so full of hope and determination. They are a constant source of inspiration.”

Friedrich’s Ataxia (FA) is a rare hereditary disease that causes damage to the nervous system. Symptoms of FA range from frequent stumbling and falling to heart disease and diabetes. It typically begins between the ages of 5 and 15 years; patients die at a median age of 35. There are currently no FDA approved drugs to treat this disease.

VP-20629, or indole-3-propionic acid (IPA), is a clinical stage drug candidate for the treatment of FA. In 2011 ViroPharma licensed worldwide rights for VP-20629 from Intellect Neurosciences, Inc., and we expect to initiate a Phase 2 study once the current toxicology work is completed.

Friedrich’s Ataxia is thought to affect about one in every 50,000 people; we are excited to be moving forward in the search for an effective treatment for this devastating disease.

C1-INH

“There are so many patients who could be helped by C1-INH. This is exciting research!”

C1 esterase inhibitor, or C1-INH, is a protein involved in regulating the body’s inflammatory response. Most people make C1-INH at normal levels, allowing their own bodies to regulate and limit inflammation. But patients with Hereditary Angioedema (HAE) have difficulty controlling swelling in their bodies. Cinryze works by providing C1-INH to people who can’t make this important protein on their own.

At ViroPharma, we believe C1-INH may benefit many other patients with debilitating diseases, and we are committed to exploring these other areas through a mix of company sponsored studies and investigator initiated work. Pre-clinical studies are being performed in a number of potential therapeutic areas including transplant, demyelination, SLE nephritis and hematology—either as ViroPharma sponsored studies or as IISs. Clinical studies include AMR, DGF and trauma (the latter being done by our colleagues at Sanquin), and we also have plans to further evaluate Cinryze in Autoimmune Hemolytic anemia.



FINANCIAL HIGHLIGHTS

	Net Product Sales	Total Operating Expenses	Operating Income	Net (Loss) Income	Diluted (Loss) Income Per Share	Cash, Cash Equivalents & Short-Term Investments	Working Capital	Total Assets	Long-Term Debt	Total Stockholders' Equity
2011 Highlights	\$544,374	\$322,246	\$222,128	\$140,659	1.68	\$459,836	\$537,280	\$1,366,797	\$153,453	\$891,124
2010 Highlights	\$439,012	\$227,312	\$211,700	\$125,608	1.47	\$505,171	\$561,019	\$1,287,574	\$145,743	\$891,135
2009 Highlights	\$310,449	\$278,319	\$32,130	\$(11,077)	(0.14)	\$331,672	\$406,375	\$1,084,451	\$138,614	\$750,387
2008 Highlights	\$232,397	\$153,652	\$78,655	\$63,960	0.84	\$275,839	\$317,413	\$1,086,129	\$161,003	\$749,334
2007 Highlights	\$203,770	\$87,974	\$115,796	\$92,105	1.21	\$584,328	\$596,819	\$771,605	\$153,572	\$558,530

*Not actual quotes

A growing portfolio

As we expand our range of products, we can bring more treatments to more patients who once had no hope.

SUBCUTANEOUS CINRYZE

"My HAE patients could really use an alternative way to administer Cinryze® (C1 Esterase Inhibitor [Human])."

Hundreds of patients use Cinryze routinely to prevent the debilitating attacks of pain and swelling caused by Hereditary Angioedema (HAE). While this therapy offers the kind of relief that has never been available before prophylactically, it currently can only be administered through an intravenous infusion—a method that can be intimidating to some patients. That's why we are aggressively pursuing the development of another delivery system for Cinryze: subcutaneous injection.

In 2011 we formed a collaboration with Halozyne Therapeutics, whose proprietary drug delivery platform is expected to enhance the delivery and absorption of subcutaneous Cinryze. In December we announced positive top line data from our Phase 2 clinical trial. We are moving into a larger Phase 2 study this year.



BUSINESS HIGHLIGHTS

Throughout 2011, ViroPharma had significant capital structure improvements such as share repurchases.

Four business development agreements were completed in 2011.

In 2011, revenues exceeded \$500 million for the first time in company history.

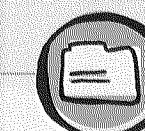
"The people of ViroPharma and their never-ending focus on patient needs is the engine that drives our success." VINCENT J. MILANO, CEO

Hope has no borders

Wherever there are patients with unmet needs, we will work to make treatments—and hope—available.



ISRAEL



INDIA



BUCCOLAM
(MIDAZOLAM OROMUCOSAL SOLUTION)
APPROVED IN EUROPE
SEPTEMBER 2011

SET FOR LAUNCH IN
2012
PLENADREN
(HYDROCORTISONE, MODIFIED RELEASE TABLET)



AUSTRALIA



Vin Milano
Chief Executive Officer



Jeff Dayno
Vice President, Medical Affairs



Jennifer Schranz
Vice President, Clinical Research



Paul Janssen
General Manager, Germany,
Switzerland, & Austria

CATHY DOESN'T TAKE AS MANY sick days as before. She's become a great mentor to the new hires.

MORE TIME SHOPPING with sis—less time worrying about attacks!

AUNT CATHY WAS ALWAYS scared to run around and play with us, but not any more. Now she's our kickball MVP!

WHEN MOM'S FEELING good, everyone's happier!

Healing Cathy's world

Typical of many patients suffering from HAE, Cathy has endured painful attacks since she was twelve years old. Two years ago she began taking Cinryze® (C1 Esterase Inhibitor [Human]), and today she's no longer in fear of her unpredictable attacks. At ViroPharma, we see this as more than the successful treatment of one patient. We understand all the ways HAE has affected Cathy's life, and the positive impact Cinryze has had on the family, friends and caregivers who make up her world.

*Not an actual patient